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**Governing the constructs of life:
What constitutes 'good' governance?**

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**Submitted in partial fulfilment of the degree of
Doctor of Philosophy in Science and Technology Policy**

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Declaration

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

Signed:

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I've always liked the saying: "life is a journey, you're going to need a lot of shoes". On the journey necessary to write a doctoral thesis, in particular, you need a lot of people to help you find the right shoes to wear along the way. It is impossible to name everyone who has helped me with this here, but there are some individuals I would like to single out for attention.

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Abstract

This thesis explores contrasting perspectives on what constitutes ‘good governance’ for human embryonic stem cell (hESC) research. It asks whether there are systematic differences between perspectives of UK and US policy actors and what kinds of patterns are discernible.

Biomedical technologies like hESCs generate complex interactions between public values, institutional interests, societal expectations and technological uncertainties. These pose serious governance challenges. Under such conditions, diverse aspects and implications of risk, ambiguity and uncertainty come into focus. We need appraisal processes that address these issues by combining quantitative and qualitative dimensions to ‘open up’ divergent governance framings. The research framework employed here uses and further develops one such elicitation and analysis process called Multicriteria Mapping (MCM). MCM combines qualitative sensitivity with quantitative precision, while also aiding transparency and reflexivity in documenting and understanding diverse stakeholder perspectives. We therefore address ‘good’ governance both as an analytical subject and as a rationale for testing a novel form of appraisal.

The analysis discerns systematic patterns in perspectives on good governance across national contexts and between stakeholders, identifying several points of convergence and divergence. We examine underlying rationales behind individual perspectives, obtaining empirical support for recent theoretical arguments concerning technology appraisal and democratic deliberation. We find national policy literatures make greater use of moral and ethical language to frame governance challenges, by comparison with stakeholders’ emphasis on institutional and socio-political factors. This suggests a more critical and cautious stance is needed towards the legitimacy language of ‘bioethics’ in policy making. Finally, we explore some of the normative implications for governance of culturally sensitive and scientifically uncertain issues.

By providing reflexive explanations of factors influencing perspectives of policy actors, this thesis makes a number of interlinked theoretical, methodological, empirical and normative contributions to understanding of how good governance of biomedical technologies is *and should be* conducted.

“If human embryonic stem cell research does not make you at least a little bit uncomfortable, you have not thought about it enough.”

Professor Jamie Thomson¹, creator of the first human embryonic stem cell line

¹ From an interview given to the New York Times on 22 November 2007 (Kolata, 2007).

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List of Abbreviations

EAB	Ethics Advisory Board
ESCRO	Embryonic Stem Cell Research Oversight
ESC	embryonic stem cell research
HERP	Human Embryo Research Panel
hESC	human embryonic stem cell
HFEA	Human Fertilisation and Embryology Authority
HFE Act	Human Fertilisation and Embryology Act
ICM	inner cell mass
IOM	Institute of Medicine
IRB	Institutional Review Board
IVF	in vitro fertilisation
MCM	Multicriteria Mapping
NAS	National Academy of Sciences
NHS	National Health Service
NIBSC	National Institute for Biological Standards and Control
NIH	National Institutes of Health
NRC	National Research Council
RATE	Regulatory Authority for Tissues and Embryos
STS	Science and Technology Studies
US	United States
UK	United Kingdom

1. Introduction

1.1 *The background context: November 1998*

In the week commencing the sixth of November 1998, the field of regenerative medicine took a major step forward. In the journal *Science*, Professor Jamie Thomson and colleagues published a three-page paper entitled “Embryonic Stem Cell Lines Derived from Human Blastocysts” (Thomson et al., 1998). The paper concludes, “Progress in basic developmental biology is now extremely rapid; human ES cells will link this progress even more closely to the prevention and treatment of human disease” (ibid., p. 1147). In the journal *Proceedings of the National Academy of Sciences*, Professor John Gearhart and colleagues published a seven-page paper entitled “Derivation of pluripotent stem cells from cultured human primordial germ cells” (Shamblott et al., 1998). Their paper concludes that human pluripotent stem cells “would be invaluable for studies of some aspects of human embryogenesis and for transplantation therapies” (ibid., p. 13730).

Human pluripotent stem cells are unique cells of the body that have the ability for both self-renewal and differentiation into any specialized type of tissue. It is these dual capacities which offer the greatest therapeutic hope for those suffering from debilitating conditions such as Alzheimer’s disease or spinal cord trauma. For this reason, human embryonic stem cell (hESC) research is among the more exciting areas of biomedical science – attracting widespread public and political attention. However, it has also unleashed a fierce battle in many countries around the world as to the moral and ethical acceptability of this area of research. What is left unsaid in the conclusions of the Thomson and Gearhart papers is that in order to realise the promised therapeutic, biological and medical benefits, human embryos must be destroyed.

This thesis investigates the implications of technological advance in this promising area of biomedicine by exploring contrasting perspectives on what constitutes ‘good governance’ for hESC research. It asks whether – and what kinds of – systematic patterns are discernible between perspectives of UK and US policy actors. Therefore, it critically examines how different understandings and determinations of good governance are constituted when scientific facts are uncertain, values are challenged and the political stakes are high.

1.2 Theoretical underpinnings

In the field of hESC research, the building blocks of human life are literally taken apart and reconstructed for scientific study. Because of this, the research comes up against socially and culturally constructed boundaries about how we define ourselves as human, posing challenges to policy-makers and societies alike. This is readily apparent when the technology is considered in a comparative context. For example, despite having similar scientific capabilities, the UK and the US have contrasting policy environments around hESC research. The issue is particularly politically charged in the US, where restrictive federal funding policies have prevailed² since the first forays into embryo and foetal tissue research in the mid-1970s. Conversely, the UK has one of the most permissive, yet highly regulated climates for hESC research in the world. The scientific details of hESC research and the relevant policy backgrounds in each country are reviewed in Chapter 2.

While these divergent policy environments are easy to observe, a singular focus on different mechanisms of government does not tell us about how and why different policy approaches come to exist in each country. As Kooiman argues,

the growing complexity, dynamics and diversity of our societies, as ‘caused by social, technological and scientific developments’, puts governing systems under such new challenges that new conceptions of governance are needed (Kooiman, 1993, p 6).

This suggests a more holistic approach to analysis with a wider governance focus is needed: one that looks at, and beyond, the institutions and instruments of government, to the wider social processes and discourses that influence the development of governance trajectories. By adopting such a ‘socio-political’ view on governance, we argue one can more readily analyse observed differences in policies, regulatory regimes and collective social problem-solving in contested areas of the biosciences. Governance is thereby positioned as a lens through which to understand how perspectives on good governance are constituted and constructed among different segments of society.

The theoretical literature on governance is reviewed in Chapter 3, in which an understanding of governance for this thesis is developed. In particular, normative conceptions of governance within the theoretical and academically oriented literature

² Despite the fact that in July 2009, US President Barack Obama overturned some aspects of the federal funding policy for hESC research established by his predecessor, President George W. Bush, there are still restrictions on federal funding of the research. In addition, many US states have restrictive regulatory policies banning research on embryos or embryonic tissue of any kind, including hESCs.

are explored. Based upon this review, three central dimensions of governance are developed and their different axes and orientations are applied within the methodological component of the thesis.

1.3 Empirical approach

The central research question of this thesis builds on the argument presented above that advances in the biosciences (or arguably in science and technology as a whole) have resulted in complex, value-laden controversies in modern societies (Davies et al., 2003). These controversies serve both to reinforce the notion of risk as a culturally embedded phenomenon (Beck, 1992) and to challenge traditional modes of political and social governance as we grapple with an increasing entanglement of cultural values and technological issues. This thesis is therefore concerned with how perspectives on ‘good governance’ for hESC research are constituted. It asks whether – and what kinds of – systematic patterns emerge between the perspectives of UK and US policy actors. The hypotheses below follow from these questions:

- *It is possible to discern discrete perspectives on good governance, and systematic differences in these between and within groups of policy actors in the UK and the US.*
- *Among these perspectives, patterns and regularities can be elucidated and analysed between and within national and cultural settings.*
- *Methods of empirical analysis can allow us to understand how the perspectives on good governance are constituted and the kinds of patterns that emerge between them.*
- *Distinctions between, and patterns within, perspectives on good governance from policy actors can be compared with the formal policy literature in each country and discernible distinctions can be analysed.*
- *Conclusions made may have normative implications for understandings of how good governance of biomedical technologies should be conducted under conditions of risk, uncertainty and ambiguity.*

In order to test these hypotheses, a methodological approach is needed that appreciates the contingencies and sensitivities shaping contrasting perspectives.

Technologies like hESC research have a powerful potential, both therapeutic and scientific, but this potential is uncertain, and to a large extent unproven, with unknown biological and long-term consequences. Conditions of scientific risk and uncertainty abound where the stakes are high, the assumptions vary and technological futures are unknown (Funtowicz and Ravetz, 1993). A range of approaches exist which, their proponents claim, enable us to arrive at robust decisions in such contexts. These more

established approaches to risk management have long enjoyed the standing of objective, ‘scientific’ methods, but their authoritative status is increasingly coming under question.

In particular, there is growing recognition of the role that social sciences have to play in decision-making (Fineberg et al., 1996). Amongst other insights, work in the field of science and technology studies has shown how expert-based and ‘technocratic’ decision analysis processes are subject to various framings and interpretations. These, in turn, can influence the ultimate policy choice (Jasanoff, 1990; Stirling, 1998; Wynne, 2001). More to the point, they can effectively ‘close down’ decision-making processes around particular sets of assumptions, while ignoring the alternatives associated with others (Stirling, 2008). This highlights the importance of acknowledging the diversity of views on risk, the ambiguities over the merits of alternative decisions, and the inherent uncertainties and ignorance that are ever present (Stirling, 2003). Procedures that can address these issues by incorporating quantitative and qualitative dimensions can “open up” divergent socio-technical framings of risk in order to explore their wider implications (Stirling, 2004, 2008).

Using hESC research as a case study, the research framework combines qualities of reflexivity, transparency and accountability in eliciting the views of divergent groups of stakeholders and analysing the perspectives for systematic patterns between groups and across national contexts. By reflexivity, we mean the framework engages symmetrically with different normative and epistemic positions, including that of the researcher. We address this by allowing for multiple units of analysis to be considered such that the central research question can be asked from, and of, multiple perspectives. This occurs at two levels, first through the eliciting of perspectives on good governance from national policy actors, and from academic and policy literatures. Second, in the analysis of these perspectives, the research question is asked of different analytical subjects and is repeatedly interrogated at each analytical step. Thus, each configuration of the data is reflexively examined in such a way that the contingencies and sensitivities framing contrasting perspectives on good governance can be explored. This reflexive approach will become clearer as it is employed in different stages of the thesis.

The particular research method used, Multicriteria Mapping (MCM), is a novel elicitation and analysis process incorporating elements both of qualitative sensitivity and quantitative precision (Stirling and Mayer, 1999). With it, one can document the nature and implications of divergent framings in appraisal – in this case, those concerning the governance of technological advance. It allows participants freely to

characterise and evaluate an unconstrained array of governance frameworks (as ‘options’) and to identify their respective strengths and weaknesses under contrasting notions of ‘good governance’ (as evaluative ‘criteria’).

As the methodology itself is so centrally intertwined with the theoretical approach of the thesis, significant attention is given to it in Chapter 4. However, it is worth pointing out here that though the unit of analysis in this thesis is ‘perspectives on good governance’, and both the elicitation and analytical methods are focussed on discerning patterns within these, this is not meant to imply that a particular, fixed set of perspectives exist that we will somehow definitively identify in this thesis. Rather, within these perspectives various elements, ideas and notions of, as well as underlying rationales and motivations for, good governance may exist that contribute to the ways in which the perspectives themselves are constituted. It is these aspects that will be referred to throughout the text. More precisely, then, it is our belief that a continuum of perspectives exists and the point is to try and understand what this set of continua might be, the patterns that exist between them, the implications for wider theory-building and the understandings of good governance that result.

1.4 Empirical findings and contributions

The findings of this study are presented in four main empirical chapters. The first of these, Chapter 5, presents a detailed review of a subset of the UK and US national policy literatures. Four themes of good governance are identified as pervasive in both sets of national literatures. These themes concern the extent to which good governance: *i*) advances scientific and technological outcomes and addresses related issues in hESC research; *ii*) encourages moral and ethical awareness of hESC research; *iii*) establishes appropriate institutions and instruments of oversight for hESC research and *iv*) is identifiably grounded in social and cultural bases. Within these themes, we find that patterns emerge between UK and US contexts. These include: *a*) contrasting framings of the nature of hESC research in relation to desired scientific and technological outcomes (or the governance trajectory), *b*) divergent presentations of the embryo coinciding with similar use of moral and ethical language to discuss governance issues, *c*) contrasting institutional perspectives on governance in terms of outcome or process-based characterisations of policy approaches, and *d*) similar levels of reliance on bioethics as a legitimacy policy advisory tool.

These four themes of good governance are used to frame comparative analysis of perspectives on good governance across national cases and empirical contexts. Chapters 6 and 7 present these findings from the 57 MCM interviews conducted for this study. Chapter 6 presents the findings as analysed in terms of aggregate national UK and US perspectives. Chapter 7 presents the findings as analysed according to various groupings of socio-political stakeholder perspectives across each national context.

We find first that systematic variations in perspectives on good governance can be discerned across and within different national settings and various groupings of stakeholders. MCM was found to offer a robust elicitation and analysis method, in that it proved capable of engaging diverse participants from contrasting national and stakeholder settings; characterising their complex and (often) divergent perspectives; and securing participants' agreement with the 'results' of their interviews. These aspects suggest there is broad applicability of the findings across the national contexts and diverse perspectives. We find that the patterns in interviewee perspectives can be analysed and interpreted according to the four themes of good governance discussed above. In addition, when compared against the patterns identified in the policy literature, distinct differences emerge between these respective literatures and national interviewee perspectives.

In the final empirical chapter, Chapter 8, the theoretical, methodological, empirical and normative strands of the research are joined together and contributions are made in four areas. We find that underlying rationales and motivations for perspectives on good governance can be distinguished according to similar imperatives to those presented in recent theoretical literatures. This lends empirical support to an emerging area of theory concerning technology appraisal and democratic deliberation. A contrast is observed between the moral and ethical characterisation of governance discussions in national policy literatures and the noticeably more socio-political and institutional characterisation of governance issues in perspectives elicited directly from stakeholders. This raises questions over policy reliance on bioethics and interdependencies between the two. The findings suggest a cautious and critical evaluation may be called for of the legitimacy language of bioethics. Finally, we argue that the systematic patterns in perspectives on good governance at both national and stakeholder levels suggest that while national comparisons are useful for identifying broad cultural tendencies, they risk overlooking the richness and complexities that exist within societies, as well as between them.

2. The science of human embryonic stem cell research and its policy context

2.1 *Constructs of Life: Stem cell science explained*

2.1.1 Overview

At the US Democratic Party National Convention in 2004, Ron Reagan Jr asked the assembled audience a simple question: “How’d you like to have your own personal biological repair kit standing by at the hospital? Sound like magic? Welcome to the future of medicine” (Reagan, 2004). With this statement, he drove home a point about the high stakes which rest upon policy decisions in an area riddled with expectations, uncertainty and controversy. Proponents of human embryonic stem cell (hESC) research promise it has the ability to provide therapies for a range of illnesses, as well as insights into the process of basic biological development. Such insights may, themselves, lead us to further therapies and technologies. Many opponents see hESC research as an affront to human dignity, believing that the use of the human embryos for research purposes is not justified and/or that scarce resources should not be spent on this area of science when more pressing issues of national health still remain.

The technologies and biomedical therapies that may enable realisation of Mr. Reagan’s promised future are born out of controversial scientific developments that are pervaded by social values, institutional interests and cultural norms. This intensifies the challenges for policy-makers and governance, more generally. While this latter point is the broader subject of this thesis, this chapter sets the stage for the discussion. It reviews the salient scientific, technological, political and regulatory aspects of hESC research with a specific focus on the US and the UK. This background will be used in Chapter 4 to justify why the US and the UK were selected as case study countries.

2.1.2 The basics of stem cell science

Developmental biologists have been studying stem cells and steadily making new discoveries about the process of embryonic development and the behaviour of stem cells since the 1950s (as described in detail by Parsons, 2004; Scott, 2006). Incremental developments (such as perfecting the culture medium, or ‘soup’, on which cells are

grown in the laboratory) and radical innovations (like the first successful nuclear transfer experiment) moved the field forward. But – until the 1980s – there was still a feeling that the great potential of stem cells had yet to be unlocked.

In 1981, a major step forward was taken when two different laboratories successfully cultured mouse embryonic stem cells (Evans and Kaufman, 1981; Martin, 1981). Three years later, Steen Willadsen, a rather unknown scientist working at the British Agricultural Research Council’s Unit on Reproductive Physiology and Biochemistry, cloned a sheep working with embryonic cells (Scott, 2006, p. 45). This latter achievement went unpublished and barely made the newspapers, but the scientific technique it employed laid the groundwork for the work of Professor Sir Ian Wilmut’s lab at the University of Edinburgh. In 1996, his lab became the first to clone a mammal from an *adult* cell (Campbell et al., 1996). Resulting pictures portraying ‘Dolly’ the clone with her genetically-identical mother made front-page headlines worldwide.

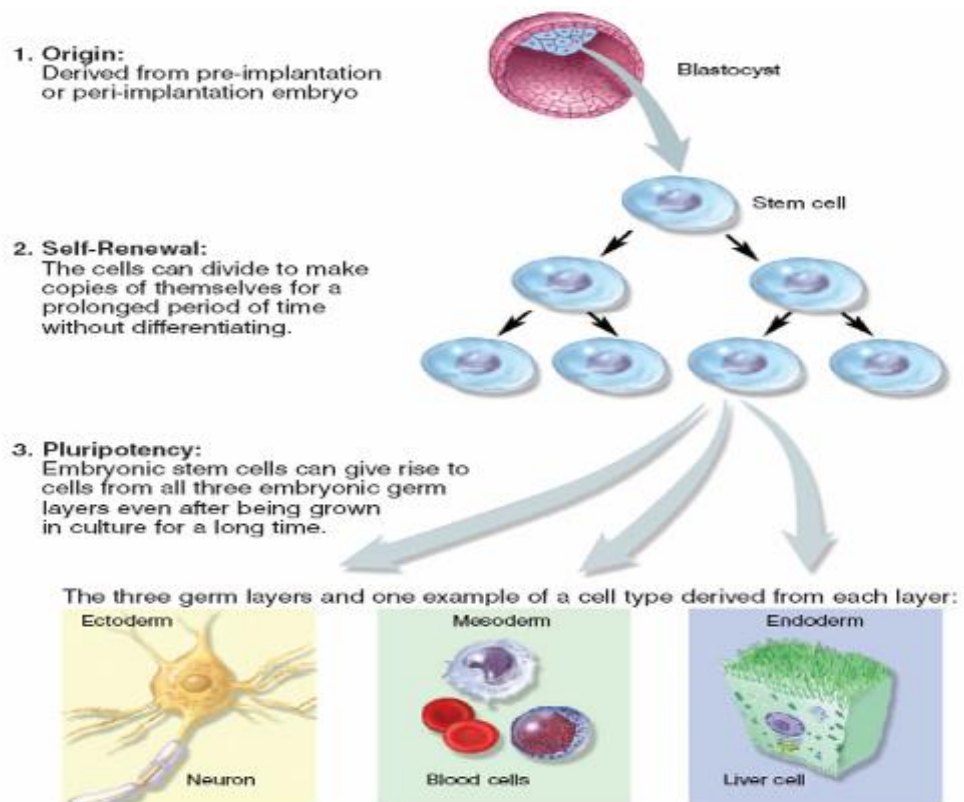
In 1998, the field’s scientific glass ceiling was broken. In publications appearing in the same week, the laboratories of Jamie Thomson at the University of Wisconsin, Madison, and John Gearhart at Johns Hopkins School of Medicine in Baltimore, Maryland, announced two scientific breakthroughs that would alter the landscape of their fields, both scientifically and politically. Thomson announced the derivation of the first pluripotent hESC lines from human embryos (Thomson et al., 1998), while Gearhart’s lab had derived pluripotent human stem cell lines from foetal germ tissue (Shamblott et al., 1998). The eyes of the world were opened to this astounding area of science. Regenerative medicine suddenly seemed less the stuff of science fiction and more a medical reality. In Congressional testimony given in December 1998, former NIH Director Harold Varmus commented that the discoveries of Thomson and Gearhart were “unprecedented” and that it was “not too unrealistic to say that this research has the potential to revolutionize the practice of medicine and improve the quality and length of life” (Varmus, 1998).

But what are these cells and how do they function? Why are they so critical to human development, and why do scientists and others think they have such great potential? The next two sections will review the scientific characteristics of stem cells and discuss their use and potential in science and medicine. Establishing these scientific principles will be critical to understanding the nuances of policy and governance challenges in this area.

2.1.3 Characteristics of stem cells

Stem cells are unique cells that have two defining characteristics: they are able to self-renew and they are, to varying degrees, undifferentiated, meaning they have the potential to develop into at least one other type of specialised ‘descendant’ cell. This dual capacity of stem cells is what offers the greatest hope and potential for applications in regenerative medicine (NRC and IOM, 2005), but, as we shall see, it is also what leads to the controversy surrounding further research in this area of biomedical science. Figure 1.1 (below) illustrates these two defining characteristics, plus a third specific to embryonic stem cells—their origin in the pre-implantation embryo.

Figure 2.1³: Characteristics of human embryonic stem cells



There are three main types of stem cells: embryonic stem cells, adult stem cells and foetal stem cells. Adult stem cells are considered to be *multipotent*. They have a limited developmental potential as they have already gone some way down a cell-specific developmental pathway, but they have not fully differentiated. Thus while a blood stem cell can further differentiate into a white or red blood cell, it cannot, to our

³ Figure 2.1 is from an article entitled ‘Embryonic Stem Cells’, published in the NIH publication *Regenerative Medicine* (Yu and Thomson, 2006, p. 2).

knowledge, differentiate into a skin cell⁴. Adult stem cells are found in differentiated tissues of the body including the brain, umbilical cord and placental blood, skeletal muscle, teeth, skin and liver.

Unlike adult stem cells, embryonic stem cells are *pluripotent*, meaning they have the ability to develop into any cell of the three main tissue layers of the body, the endoderm, ectoderm and mesoderm (shown above in Figure 2.1). Pluripotent stem cells can divide indefinitely in culture and are considered extremely malleable, that is, researchers can manipulate them and coax them to become different tissue types without the cells losing any cellular function. Embryonic stem cells are derived from a primitive, undifferentiated state of development: the pre-implantation embryo (NAS, 2006). Herein lies much of the controversy surrounding hESC research as, currently, the only way to derive and study ES cells results in the destruction of a developing embryo (described below). The final class of stem cells for which there is a scientific classification are *totipotent* stem cells. These have the potential to form a whole new organism in and of themselves (an ability pluripotent cells do not possess) (Holland et al., 2001) and they would have to be derived from the very early embryo, or zygote stage (see below). Researchers do not derive embryonic stem cells from such an early stage of development and most embryonic stem cells are, therefore, discussed in terms of pluripotency.

Finally, foetal stem cells are derived from the gonadal ridge⁵ of fetuses in an early stage of development (NRC and IOM, 2002). These stem cells are technically multipotent in character and so are not as easy to work with as ES cells (NRC and IOM, 2005). However, they have been shown to give rise to cells of all the main tissue layers, proving they retain some features of pluripotency. Much of the remaining discussion in this chapter will focus on *embryonic* stem cells, but there will be some space devoted to recent developments in the science that relate to alternatives to embryonic stem cells.

2.1.4 Deriving embryonic stem cells

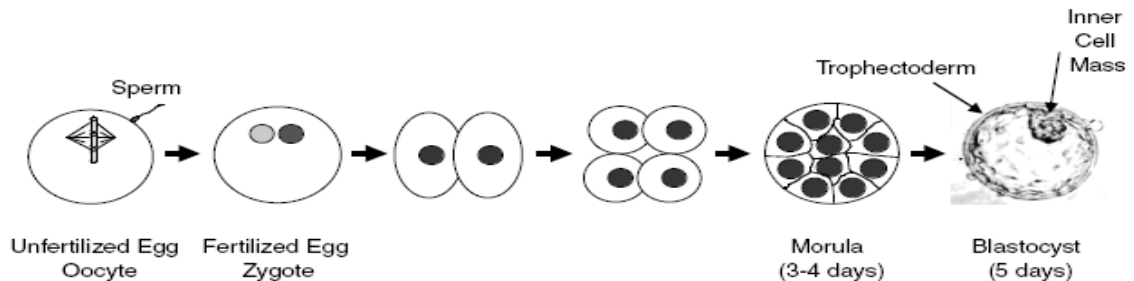
Embryonic stem cells can be derived in two main ways: from the inner cell mass of a developing blastocyst, or by nuclear transfer (NT). Both methods require that the embryo be destroyed at an early stage in its development, usually around the fifth or

⁴ However, recent developments in the science have shown that fully differentiated cells, such as skin cells, can be induced to return to their pluripotent state. These cells, known as induced pluripotent cells (iPS), will be discussed later in this chapter.

⁵ The gonadal ridge eventually develops into eggs or sperm in the adult human being.

sixth day after fertilisation. However, we need to have a basic understanding of the development of the embryo, from the point of fertilisation through to implantation of the embryo in the uterine wall, before discussing how these derivation processes work.

Figure 2.2⁶: Preimplantation development of the embryo



As shown in Figure 2.2, in its earliest stages the ‘embryo’ is not referred to as an embryo, but by a series of terms that describe the different stages of development. In fact, before the embryo is considered to be a foetus, it passes through over 20 stages of embryonic development that are scientifically distinct. At the earliest stage, immediately after fertilisation of the oocyte by the sperm, the embryo is referred to scientifically as a ‘*fertilized egg zygote*’, or simply a *zygote*. The zygote then enters a cleavage stage where it divides approximately once per day, with no net growth in its size. Cleavage continues until Day 3 or 4, at which point a ball of cells called the *morula* begins to form. At Day 5, the morula has hollowed out and is now a *blastocyst*. The blastocyst has two distinct cell types—an outer layer of cells called the *trophectoderm* (which becomes the placenta) and an inner layer of cells called the *inner cell mass* (ICM). Throughout these early growth stages, the developing embryo is no bigger than the dot above an ‘i’ on a piece of paper.

It is the pluripotent cells of the ICM that will eventually grow, multiply and differentiate into all the cells of the human body. However, the cells of the ICM only exist in this state for a brief period of time. At Day 6, the *blastocyst* is implanted into the uterine wall and the placenta begins to develop from the *trophectoderm*. At this point, the cells of the ICM begin further differentiating into the cells and tissues of the foetus, forming first what is known as the *embryonic disc*. At about two weeks after fertilisation, “the first recognisable features of the embryo proper will appear” (Warnock, 1985). The first of these, and most significant for regulatory purposes as will

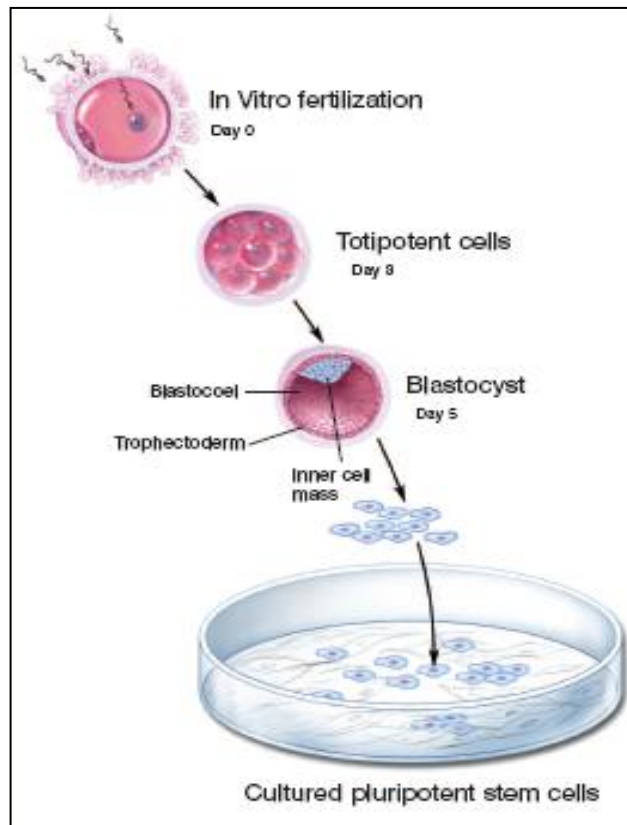
⁶ Figure from the NAS Guidelines for Human Embryonic Stem Cell Research (NRC and IOM, 2005, p. 30)

be shown later in this chapter, is the *primitive streak*. This appears as a grouping of cells at one end of the embryonic disc at the fourteenth or fifteenth day after fertilisation. It is one of the earliest recognisable features of the developing embryo. One month after fertilisation, cells in the developing embryo begin to work together, a primordial heart begins to beat, and by two months after fertilization, all the major organ systems have developed (Scott, 2006). It is at this point, approximately seven or eight weeks after fertilisation, that the ‘embryo’ phase is considered to end and the foetal stage of development begins.

As alluded to earlier, it is at the earliest stages of embryonic development that embryonic stem cells are derived. The derivation process (see Figure 2.3) first requires extracting the cells of the ICM from the blastocyst just before it would (in theory) be implanted into the uterine wall, usually around Day 5 or 6.⁷ Once the ICM is removed from the blastocyst, the cells are transferred to a special culture medium that contains the right set of nutrients for the cells to continue growing. This medium is meant to simulate the environment the cells would experience in the developing blastocyst if it were frozen in time. Therefore, the culture medium allows the cells to grow in their ‘stem cell’ state indefinitely. Scientists can then take stem cells from this medium and stimulate them to differentiate into specific tissues for scientific study.

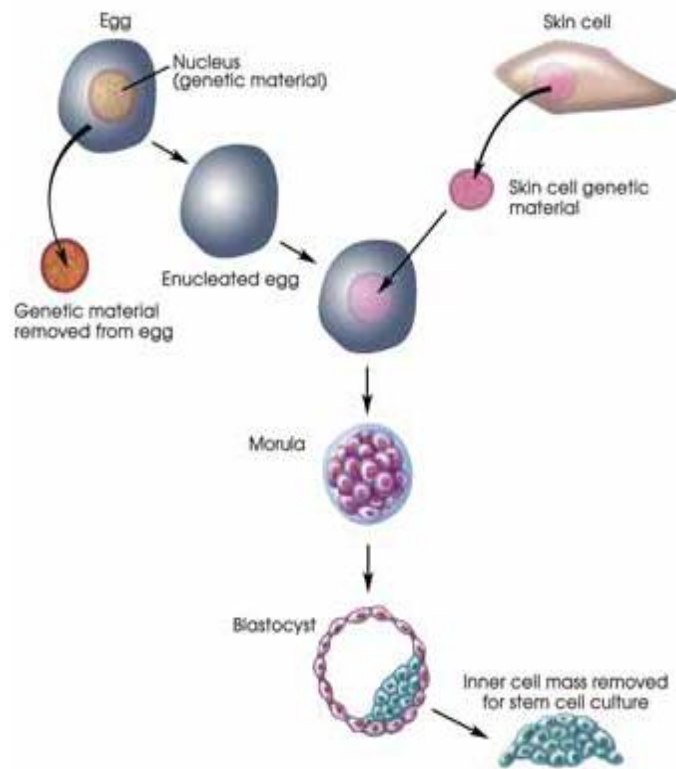
⁷ We say ‘in theory’ because the process of derivation is actually conducted in vitro, not in utero, so there is no ‘real’ uterine wall for the blastocyst to attach to when ES cells are derived in the laboratory.

Figure 2.3⁸: Derivation of embryonic stem cells from a fertilized embryo



Pluripotent embryonic stem cells can also be derived through a process called nuclear transfer (NT). Figure 2.4, below, illustrates the most commonly known NT process called somatic cell nuclear transfer (SCNT). In SCNT, a single cell is taken from an adult somatic (or fully differentiated) cell and the nucleus of that cell is then removed. This nucleus is then placed into a separate ‘donor’ egg which has also been enucleated. The newly created cell is given a stimulus to encourage it to begin growing and dividing as a blastocyst. As above, at the appropriate time the ICM is then removed from the blastocyst and a culture of embryonic stem cells is made that are genetically identical to the original adult somatic cell. Nuclear transfer can also take place using other types of cells, for example donated cells from another developing blastocyst.

⁸ Figure 2.3 is from an article entitled ‘Embryonic Stem Cells’, published in the NIH publication *Regenerative Medicine* (Yu and Thomson, 2006, p. 1).

Figure 2.4⁹: Somatic Cell Nuclear Transfer

By using the NT processes, the embryonic stem cell line that is created is genetically identical to whatever ‘donor’ cell it came from. This is one reason why this technique is commonly pointed to as having a great potential to lead to actual therapies from stem cell research. SCNT is the technique that was used to clone Dolly the sheep and it is one you could envision being used to create *patient-specific* stem cells that can then be injected back into the patient with the hope they will replace the damaged tissue. For this reason, SCNT is sometimes referred to as ‘therapeutic cloning’. However, to date no one has been able to clone a human embryo, nor derive a human embryonic stem cell line, in this way or through any other procedures.¹⁰

For both methods of deriving embryonic stem cells, there are three main sources of hES cells: blastocysts remaining from IVF clinics or fertility treatment centres and donated for research; blastocysts generated from donated gametes; or products of NT.

⁹ Figure 2.4 is from the National Academy of Sciences publication *Understanding Stem Cells* (NAS, 2006, p. 6)

¹⁰ In November 2007 a primate embryo was successfully cloned for the first time (Byrne et al., 2007). This development allayed many fears that there was some unknown characteristic of primate embryos, and hence human embryos, that would prevent successful cloning at any point. Then, in January 2008, Stemagen (a San Diego, CA based embryonic stem cell research company) published a paper claiming they had created human blastocysts using SCNT. These blastocysts were only viable up to various stages of development and never reached a stage where the ICM could be extracted. See (French et al., 2008) for further details.

Out of these three sources, egg donation, in particular, is a recent topic of much debate. There are divided camps on whether women should be paid to donate their eggs to research, and, if so, how much. Some argue this is a necessary scientific resource and women should be compensated for the difficulty and hardship associated with egg donation. Others argue this will create an unwanted market for women's eggs and will pose too great a risk to the health of the woman. Recent legislation in the UK has made it legal for scientists to use animal oocytes as the 'vessel' in which to grow the blastocyst to the appropriate stage for removal of the ICM and derivation of an embryonic stem cell line. Scientists argue that the creation of so-called 'cytoplasmic-hybrid' embryos is a welcome alternative to egg donation in the light of egg donation problems, but opponents argue this would amount to egregious ethical violations and could lead to the creation of 'Frankenbunnies' (Watts, 2009).

In addition to the methods of deriving hES cells from blastocysts, scientists have had some success in identifying possible alternative sources of embryonic stem cells that do not require the destruction of an embryo. However, there is some debate as to how viable these alternative methods are and the quality of the hES cells they produce. For example, in 2007, Dr. Anthony Atala and colleagues isolated hESCs from amniotic fluid and showed they grow just as fast as embryonic stem cells and exhibit strong pluripotent characteristics (De Coppi et al., 2007). In the wake of that announcement, however, it was the researchers themselves who stressed their findings should not be used as an argument for discontinuing embryonic stem cell research (Weiss, 2007). Their point was that all scientific opportunities should be pursued and different methods had different advantages.

In November 2007, research groups in Japan (Takahashi et al., 2007) and at the University of Wisconsin (Yu et al., 2007) reported they had successfully de-differentiated somatic cells, meaning they had literally 'wound back the clock' on adult somatic cells. These *induced pluripotent stem cells*, or iPS cells have (so far) exhibited many of the traits that characterize embryonic stem cells¹¹, but with none of the controversy surrounding the destruction of an embryo. Since this is such a new area of stem cell biology, studies are ongoing to compare them to pluripotent hESCs, which

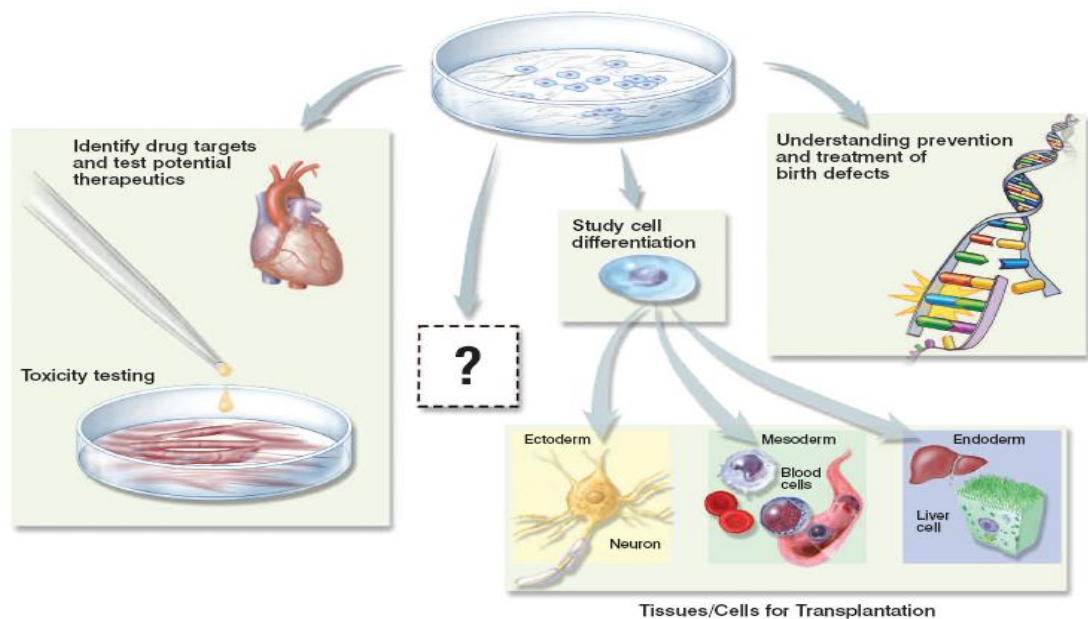
¹¹ Mouse iPSCs show important characteristics of pluripotent stem cells, including expressing stem cell markers, forming tumors in all three germ layers, and being able to contribute to many different tissues when injected into mouse embryos at early stage of development (Takahashi and Yamanaka, 2006). Human iPSCs also express stem cell markers and are capable of generating cells characteristic of all three germ layers (Takahashi et al., 2007; Yu et al., 2007).

continue to be described as the ‘gold standard’. However, creating iPS cells requires using viral vectors. These vectors carry genes that reprogram the original cell to its pluripotent state, which is useful for the science, but one of these viral vectors is known to cause cancer, which means the cells could not be used for medical therapy. Nonetheless, many disease-specific stem cell lines have already been created and scientists are able to study their behaviour in vitro. It is seen by many scientists and non-scientists alike as an exciting development; one that could potentially obviate the need to use embryos in research, but that day is still a long way off.

2.1.5 Human embryonic stem cell technologies

As has been alluded to in the preceding discussion, the pluripotent characteristic of embryonic stem cells suggests they may have wide-ranging uses. As illustrated in Figure 2.5, there are generally three main applications wherein lies the greatest potential for the application of embryonic stem cell technology.

Figure 2.5¹²: Some of the Promises of Stem Cell Research



First, it is claimed hESC research can lead to improvements in our understanding of basic biological development. Such improvements could lead to insights into treatment of fertility problems or prevention of birth defects. Second, embryonic stem cells can be used by the pharmaceutical industry to test the properties

¹² Figure 2/5 from an article entitled ‘Embryonic Stem Cells’, published in the NIH publication *Regenerative Medicine* (Yu and Thomson, 2006, p. 3).

of new drugs, thereby providing ways to improve their safety and efficacy. Currently, many new drugs are tested on animal models because no human cells exist for the study of drugs at the pre-clinical trial stage. If, for example, a stem cell line of human heart cells were developed, researchers could use these cells to better understand how the drugs work. Efficacy and safety could be improved and tested even before clinical trials on humans began. This would be a major improvement in the pharmaceutical industry's testing model and we are indeed already beginning to see the positive effects of stem cell science in this regard (Baker, 2010).

Finally, and perhaps most widely hoped for, is the development of hESC technologies for use in medical therapies. Such 'regenerative medicine' technologies could be restore or repair damaged tissue in the body, such as heart, neural, pancreatic, or spinal tissues. Stem cells have already been used in such a regenerative way for many years in the use of haematopoietic stem cells (found in bone marrow) to treat blood cancer patients. A successful bone marrow transplant can mean regeneration of all the cells of the haematopoietic system, including red blood cells, platelets, lymphocytes, etc. (Domen et al., 2006).

However, though haematopoietic stem cells have been proven to work in therapeutic contexts, they are adult stem cells and thus have limited (or no) therapeutic potential for other tissue types. Embryonic stem cells, on the other hand, are more versatile and could be used, for example, to generate cardiomyocytes for heart disease, neural cells for neurologic diseases, islet cells for diabetes, skin grafts for burn victims, and so on. The list is long and the hopes of patients afflicted with debilitating and degenerative diseases are high. From the period 2006-2009, the US National Institutes of Health (NIH) spent \$343 million on human embryonic stem cell research, and \$3.78 billion on stem cell research overall. Estimates for spending in 2010 are \$1.182 billion for stem cell research and \$137 billion for hESC research (NIH, 2010). US states active in funding stem cell research are estimated, as of 2007, to be spending \$528 million per annum (Fossett, 2007). Private funding estimates are difficult (if not impossible) to obtain, but one estimate done in 2007 calculates \$1.7 billion was spent by a small group of major US advocacy groups, philanthropic foundations, and others (ibid.).

Across the Atlantic, the 2005 UK Stem Cell Initiative report called for an increase of £200-272 million in basic stem cell research over the 10 year period from 2005-2015 and a further increase of £83-87 million in clinical and translational research over the same 10 year period, coupled with a concurrent rise in National Health Service

(NHS) research and development (R&D) funding of £36m per annum. These sums are large and serve to underscore the weight and importance accorded by national governments and funders of research in this area. However, they do not tell the whole story of how research is carried out in each country, nor the policies that are in place to oversee it. The remainder of this chapter sets out the policy histories pertinent to human embryonic stem cell research in the US and the UK, identifying the social, cultural, historical and legal contexts in which policy has developed over time.

2.2 Governance of human embryonic stem cell research in the United States

2.2.1 Overview

In the US, the history of embryo research seems marked by continued uncertainties, political contention, and mixed regulatory environments. Until recently,¹³ federal and legislative regulations restrict federal funds for the majority of hESC research, but there are a variety of approaches being adopted at the state level and within individual research institutions. This inconsistent and rapidly changing research and policy landscape has been described by several commentators as akin to a ‘patchwork quilt’ (see, for example, NRC and IOM, 2005). The next section looks at the history of foetal tissue and embryo research policy in the US, as it is this history that has had a significant impact on the current policy and regulatory climate for hESC.

2.2.2 History of foetal tissue and embryo research policy in the US

Many would argue that the debate over hESC research is “inextricably linked with the abortion debate”, which has polarised American society (Wertz, 2002, p. 143) since the 1973 Supreme Court decision ‘Roe v. Wade’. The politics of abortion clearly play a major role when it comes to the status of the embryo and hESC research, but we will not be addressing the full scope of that debate in the discussion here. This is partly because a recounting of the policy history of that debate, specifically, is outside the scope of this thesis. Though the issues shaping the abortion debate do intersect with the

¹³ See footnote 1 on page 2 related to the recent changes to federal policy under President Obama which occurred during the course of writing up this thesis. All empirical research conducted for the thesis was undertaken during the term of President George W. Bush, when more restrictive federal policies prevailed, and so these will be the focus of policy history text below.

issues around embryo research (for example, concerns over the moral and legal status of the embryo), the purpose of this thesis is to consider multiple and symmetrical perspectives on hESC research. Therefore, we need (quite deliberately) to avoid the polarisation that is present in the abortion debate, but still allow for the views which frame that debate and, subsequently, those on hESC research, to be addressed. The methodology employed in this thesis can address this, and does not require a full recounting of the policy history of abortion to do so.

Instead, we will start our story in the late 1960s when the American scientific community, as well as the national public, were shocked to learn about the human rights abuses in the Tuskegee Syphilis Trial. In order to understand the long-term effects of syphilis, researchers with the U.S. Public Health Service denied treatment to 399 poor African American men and instead talked them into participating in a study of which they were told little. The researchers were simply interested in studying the progression of the disease and so withheld all treatments from the men (Fairchild and Bayer, 1999). When the study was exposed in the national media, outrage followed. It was, in many ways, a final straw in a list of growing concerns about the conduct of research on human subjects and in the early 1970s the US government set out to reform and overhaul the regulatory system for human subject research. A few years later, the U.S. Congress passed the National Research Act of 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. This Commission was to make recommendations on the ethical conduct of human subjects research in the US, including foetal tissue research. In this latter area, the Commission recommended that an ethics body be established to oversee and advise on federally funded research in this area.¹⁴

The timing was apt. Just as the newly created Ethics Advisory Board (EAB) was coming into existence, the world's first 'test-tube baby', Louise Brown, was born in 1978 through the help of in vitro fertilisation (IVF) technology. With this birth, the need to specifically address the use of embryos and foetal tissue in research became more immediate. Under Federal regulations (45 CFR 46), the EAB was to oversee and approve all federally funded research on fetuses and foetal tissue that originated from abortions. The EAB also considered the ethical issues of the research, recommending

¹⁴ Due to the nature of federal funding for biomedical research in the US, restrictions on federal funding are generally respected by institutions that are recipients of federal funds, even for research funded in other ways, to prevent the risk of losing eligibility for federal funding of other research projects.

that federal funding of research aimed at increasing the safety and efficacy of IVF and embryo transfer would be acceptable, provided ethical safeguards were followed (NIH, 1994). However, in 1980 the charter for the EAB expired and President Reagan never renewed it, an action that resulted in a de facto moratorium on all federally funded foetal tissue, IVF and embryo transfer research for the next 13 years.

Federal regulations (45 CFR 46) remained on the statute books until 1993 when the National Institutes of Health (NIH) Revitalization Act of 1993 was passed and the regulatory requirement for EAB review was removed. With this Act of Congress, it was made explicit that funding of “peer reviewed and approved research proposals involving assisted reproductive technologies” would be permitted (from NIH, 1994, p. 1). However, before funding any research of this nature, NIH commissioned an expert panel to study the moral and ethical issues that were involved. The Human Embryo Research Panel (HERP) recommended that federal funds should be used to fund human embryo research, including the creation of human embryos, provided they were not used for human cloning (NIH, 1994). After receiving thousands of letters expressing unease with the idea of federal funding of embryo research, President Clinton rejected the panel’s findings on this latter point.

In 1995, the U.S. Congress created a more permanent barrier to federal funding of embryo research. The Dickey-Wicker Amendment was passed in 1995 as a rider to the annual NIH appropriations bill. It essentially states that no federal funds can be used to create human embryos or to conduct research in which they are destroyed. This amendment has been attached to every single appropriations bill since, seeming to create a permanent roadblock to federal funding of any embryo research, including hESC research.

With the derivation of the first hESC line in 1998, however, the NIH requested a legal opinion on whether the Dickey Amendment precluded them from funding such research. Harriet Rabb, General Counsel to the Department of Health and Human Services in the Clinton Administration, concluded that the amendment does not explicitly prohibit research on embryos once they have been destroyed (Rabb, 1999). This essentially gave the green light to the NIH to begin funding research on hESCs, so long as the *initial* creation of the stem cell lines was done using private funds. The NIH began to develop guidelines for hESC research and published them in final form in the Federal Register on August 25, 2000 (Kirschstein, 2000). After a period of consultation

and further revision, the NIH began receiving the first grant applications for hESC research in the spring of 2001.

By this time, however, President George W. Bush had been elected and his campaign rhetoric suggested he was not supportive of hESC research. Nonetheless, the NIH Human Pluripotent Stem Cell Research Group was set to meet on 25 April 2001 to review the first stem cell research grant applications. However, the meeting was abruptly cancelled so that a full scientific review could be conducted (Weiss, 2001). Three months later, President Bush used the first nationally televised speech of his presidency to declare that no federal funds could be used for embryo research where the embryo would be destroyed or harmed. Therefore, federal funds could only be used for research on embryos or embryonic stem cell (ESC) lines that were created on or before the date and time of his speech (9:00pm EST on 9 August 2001).

President Bush presented his declaration as a compromise, claiming that approximately 78 hESC lines already existed and these would be sufficient for researchers to be able to continue research in what he acknowledged was a promising field with medical potential. However, it quickly became clear that only 23 of these lines were available for use by researchers, and none of them could ever be used to develop medical treatments because they were originally grown on mouse feeder cells, making them unsuitable for use in humans (Scott, 2006). As time went on, the number of viable cell lines decreased further, and researchers were left looking elsewhere for funding and guidance as to the conduct of the research itself.

2.2.3 A regulatory patchwork for hESC research?

Aside from President Bush's restrictions on federal funding for hESC research and the Dickey Amendment, there were no federal regulations or legislation specific to hESC research at the time this thesis research was conducted. However, it would be misleading to say it was an unregulated area of research as federal regulations broadly covering the field of biomedicine apply to both privately and publicly funded hESC research. These include:

- Human subject protections for donors of oocytes, somatic cells and embryos;
- Medical privacy protections;
- Laboratory standards laws enforced through the Clinical and Laboratory Amendments of 1988 and the Fertility Clinic Success Rate and Certification Act of 1992;

- The Public Health Service Act that imparts statutory authority to the U.S. Food and Drug Administration (FDA) to regulate biologics,¹⁵ including embryonic stem cells, should it choose to;
- Institutional Review Boards (IRBs) set-up to oversee federally funded research at individual research institutions across the country; and
- FDA standards of laboratory practice for any research supporting applications to the FDA for regulatory approval (NRC and IOM, 2005).

In addition, many states have passed legislation designed to either restrict or to fund and support hESC research. Thus, as we pointed out before, many liken the US policy situation for hESC research to a regulatory ‘patchwork quilt’. In this regard, it is important to note two things. First, although FDA regulations do not apply until one has moved to clinical trials of stem cell therapies, publicly and privately funded researchers involved in basic research still consider the regulations to be applicable, where possible. This is because if acceptable derivation practices are not followed in laboratory research, hESC lines will not be eligible for use in clinical trial.

Second, President Bush’s federal restrictions and the Dickey Amendment, only apply to *publicly funded* research in the US. Privately funded research is, strictly speaking, unregulated unless it involves human subjects or clinical trials, at which point FDA regulations would apply. This distinction between publicly and privately funded research is important to keep in mind throughout the discussion of hESC governance in this thesis.

Though the regulations listed above broadly apply to hESC research, they are not comprehensive and were not designed with hESC research in mind. Partly for this reason, the National Academy of Sciences (NAS), widely seen as the informal advisor to the US government on issues of science and technology, released a report in 2005 setting out suggested guidelines for hESC research (NRC and IOM, 2005). The main recommendation is that all institutions involved in hESC research should establish local Embryonic Stem Cell Research Oversight (ESCRO) committees comprised of scientific, legal, and ethical experts, as well as educated members of the public. These ESCRO committees are meant to act as Institutional Review Boards¹⁶ and approve applications to conduct hESC research, regardless of the source of funding. In addition to this, the

¹⁵ The term ‘biologics’ is used to refer to a range of biological products regulated by the U.S. FDA, including vaccines, blood and blood components, somatic cells, gene therapy, tissues and recombinant therapeutic proteins.

¹⁶ Institutional Review Boards, or IRBs, are a central component of the US federal funding system of oversight. Each institution that receives federal funding must have an IRB approval process and all research, regardless of its funding source, must receive IRB approval prior to commencing.

guidelines also recommend that a national panel should be formed to oversee the main issues involved in research on a continuing basis. These guidelines were generally welcomed by the scientific community in the absence of any concrete federal guidance, but have also been criticized for being incomplete and a poor substitute for NIH-like guidance (Phillips et al., 2006).

Completing the regulatory patchwork ‘picture’ of patchwork regulations is the role of individual states in the US federal system of government. Some states have banned embryo research, while others have passed multi-billion dollar bond initiatives for state-of-the-art research centres (NRC and IOM, 2005). However, as pointed out in a report by Fukuyama and Furger (2007), attempts by states to act in this area are often through narrow legislative bans or targeted legislation that is tightly defined. Where legislation is broader or includes provisions for research oversight, there are still overlaps and gaps between state and federal regulations (Winickoff, 2006; Fukuyama and Furger, 2007). Annex A contains details of initiatives and policies in individual states. In all, 12 states have passed legislation actively supporting stem cell research and have provided funding for the research to be conducted.

To summarise, the US policy history for hESC research and current mechanisms of oversight seems to be a process marked by inconsistencies, political minefields and regulatory ‘thickets and gaps’ (Baker, 2008). We will now look at the UK which has, in contrast, a rather more straightforward policy history, which has resulted in a relatively permissive regulatory framework.

2.3 Governance of human embryonic stem cell research in the United Kingdom

2.3.1 Overview

Human embryonic stem cell research was explicitly permitted in 2002 by an act of the UK Parliament after a report by the House of Lords recommended that the Human Fertilisation and Embryology Act of 1990 (HFE Act) be amended to include hESC research in its remit. In the same year, the National Institute for Biological Standards and Control (NIBSC) opened a stem cell bank, which provides stem cells to any company or institution that demonstrates the appropriate ethical, peer review and informed consent procedures are in place. In the Chancellor’s Budget report in March

2005, the UK Stem Cell Initiative was announced to great fanfare, with the claim that it would pave the way for the UK to become a world leader in embryonic stem cell research (UK Stem Cell Initiative, 2005).

These are just a few examples of recent policy and political moves in the UK, but they underscore a generally more actively supportive government attitude to hESC research. The reasons for this will be discussed over the course of this thesis, but below we will review the UK policy history, starting with the initial regulation of foetal tissue and embryo research.

2.3.2 History of foetal tissue and embryo research in the UK

The birth of Louise Brown in 1978 was “a considerable achievement” that simultaneously raised both hopes and anxieties amongst the British public:

long sought, at last successful, [it] opened up new horizons in the alleviation of infertility and in the science of embryology... However, there were also anxieties. There was a sense that events were moving too fast for their implications to be assimilated (Warnock, 1985, p 4).

Sentiments like these were pervasive and prompted the UK Government’s Department of Health and Social Security to launch an inquiry in 1982 in order to consider the social, legal and ethical consequences associated with reproductive technologies, including the use of embryos in research (Mulkay, 1994). The Committee of Inquiry (the ‘Warnock Committee’) was chaired by Mary Warnock. Its final report to Parliament (the ‘Warnock Report’) left a lasting legacy on the field of embryo research, both nationally and internationally, through its recommendation of the ‘14-day rule’ for embryo research (discussed in more detail below). Moreover, the deliberations, arguments, and recommendations presented in the Warnock Report form the cornerstone of all subsequent UK legislation and national dialogue regarding the regulation of IVF technologies and embryo research, including hESC research¹⁷. Therefore, it is important to look at its approach in some detail¹⁸.

The Warnock Committee’s remit was:

to consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards

¹⁷ As pointed to in many Government reports on the subject since. See for example, the report from the House of Commons Science and Technology Select Committee, *Human Reproductive Technologies and the Law* (2005) and the Department of Health’s *Review of the Human Fertilisation and Embryology Act* (DoH, 2006).

¹⁸ Though the Committee deliberated on the full range of issues relevant to fertilization and embryology, the focus here will be on their discussions concerning the use of human embryos in research.

should be applied, including consideration of the social, ethical and legal implications of their developments; and to make recommendations (Warnock, 1985, p. 4).

On the issue of using human embryos in research, the Committee started by going “straight to the question of *how it is right to treat the human embryo*” (emphasis in original, *ibid.*, p. 60). In order to determine this, the Committee considered ethical, legal and scientific views on the embryo. The ethical considerations centred around three principal views on the embryo: 1) considering the embryo as equivalent to a human life and, therefore, entitled to full human rights, a view adopted by the Catholic Church; 2) a point of view roughly equivalent to that of the Church of England and Judaism, which see the development of personhood as a gradual process; and 3) a view which sees the embryo as no more than a collection of cells. The Committee found the second point of view to be the most appropriate and supported this finding with legal and scientific considerations (discussed below).

In considering the permissibility of embryo research, the Committee looked at the current legal framework for the embryo and any protections afforded to it. Though protections existed for the embryo *in vivo*, there was very little in the law to protect the *in vitro* embryo that was to be used in research. They found this to be unsatisfactory and concluded that the “the embryo of the human species ought to have a special status” and that this “status of the embryo is a matter of fundamental principle which should be enshrined in legislation” (*ibid.*, p. 63).

In regard to scientific considerations, the Committee received evidence from a number of sources, including the Royal College of Obstetricians and Gynecologists, the British Medical Association, and the Medical Research Council on the scientific status of the embryo. The Committee wanted to fully understand the biological issues surrounding human development and what the technical distinctions were in the stages of development. Largely because so much was, and is, unknown about the development of the embryo, there was little consensus among the different professional bodies as to the point at which the embryo could be said to ‘become’ a human individual.

The Committee members themselves, however, were agreed that a cut-off point for research be established. In light of the ethical, legal and scientific inputs, they arrived at the point at which the neural system begins to develop because, they felt, the presence of a neural system suggests the early embryo might then be capable of feeling

pain¹⁹. This point is believed to happen around 14-15 days after fertilization with the formation of the ‘primitive streak’, as discussed earlier in this chapter. The primitive streak gives rise to many cell types, including the neural groove from which the entire nervous system later emanates. Thus, the Committee felt that the development of the primitive streak “marks the beginning of individual development of the embryo” (Warnock, 1985).

Taking the legal, ‘special status’, of the embryo together with a gradualist approach to the development of personhood and the scientific views on biological development, final recommendations on the use of embryos in research were made. The Committee concluded that: *i*) research using *in vitro* human embryos should only be conducted with a license, *ii*) that the ‘special status’ of the embryo require careful ethical and regulatory oversight, *iii*) that research on human embryos should not be conducted past 14 days of development, and, *iv*) that oversight of research should be conducted by the same licensing body recommended to regulate all human fertilization and embryology (Ibid).

In 1990, five years after Mary Warnock and her committee issued their report, the Human Fertilisation and Embryology Act of 1990 (HFE Act) was passed. This Act sets out the rationale for embryo research and establishes an independent Human Fertilisation and Embryology Authority (HFEA) to regulate and license, on a case-by-case basis, all reproductive technologies and practices, including embryo research. Under Schedule 2 of the Act, a license cannot be granted to conduct research using an embryo “unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research” (UK Government, 1990, paragraph 3(6)). There are five purposes under which the HFEA can authorise research:

- a) promoting advances in the treatment of infertility,
- b) increasing knowledge about the causes of congenital disease,
- c) increasing knowledge about the causes of miscarriages,
- d) developing more effective techniques for contraception,
- e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, or
- f) for other such purposes as may be specified in regulations (UK Government, 1990, paragraph 3(2)).

¹⁹ However, as pointed out by many scientists and doctors in evidence to the committee, we have no way of scientifically determining whether the embryo is capable of feeling pain at this point.

Though the Act has undergone changes in recent years, as will be discussed below, the six research purposes, the respect for the special status of the embryo, and the case-by-case consideration of licenses are still central to the HFEA's oversight of embryo research and reproductive technologies.

The importance of the Warnock Report reaches far beyond its initial advisory role. Though contentious at the time,²⁰ the Committee's findings established ethical and moral principles on which subsequent legislation and national discussion could rest. We will now look at how recent policy developments, in light of advances in hESC technology, have played out against this background context.

2.3.3 Permissive regulations for hESC research?

With the announcement in 1998 of the derivation of human embryonic stem cell lines, the UK government, like the US, began to think about what regulatory context this research might be conducted within. It became apparent that the current remit of the HFE Act, though covering human embryo research, was ambiguous when it came to human embryonic *stem cell* research. As an example of this, a strict interpretation of the definition of the embryo in the 1990 Act—"a live human embryo whose fertilisation is complete"—raises questions about the permissibility of nuclear transfer technologies where no fertilisation occurred.

In 1999, a special Expert Committee, chaired by the Department of Health's Chief Medical Officer, was asked to "undertake an assessment of the anticipated benefits of new areas of research using human embryos, the risks and the alternatives and, in light of that assessment, to advise whether these new areas of research should be permitted" (DoH, 2000, p. 2). The Committee ultimately concluded that "the great potential to relieve suffering and treat disease meant that research was warranted across the whole range of possible sources of stem cells in the first instance, including embryos" (ibid., p. 9). In light of these findings, the Government drafted legislation which was debated in Parliament and eventually passed on 19 December 2000 as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (2001a). These regulations added three new research purposes to the existing six in the original HFE Act:

- g) increasing knowledge about the development of embryos,

²⁰ This was acknowledged by Mary Warnock, herself, in a special introductory chapter published with the final report in 1985 (Warnock, 1985).

- h) increasing knowledge about serious disease, or
- i) enabling any such knowledge to be applied in developing treatments for serious disease (ibid.).

Following the enactment of these regulations, the House of Lords Select Committee considered whether an additional law was needed to regulate human cloning techniques, namely, nuclear transfer techniques. After much deliberation among peers, the report by the House of Lords found nuclear transfer techniques to be ethically acceptable, provided they were never used to clone a human being. To this end, the Human Reproductive Cloning Act of 2001 was passed, which officially outlawed human reproductive cloning (2001b).

In 2005, the House of Commons Select Committee on Science and Technology reported on their year-long review of human reproductive technologies and the law (DoH, 2005b). They expressed views on a variety of issues related to the Act, including whether a legal definition of the embryo should be incorporated into the Act, the robustness of the decision-making processes of the regulator, and whether a single regulatory body for all reproductive medicine and human tissues (with the suggested title of the Regulatory Authority for Tissues and Embryos, or RATE), should be created. In late 2006, the Department of Health published a White Paper on the review of the HFE Act, which was to become the basis for the Draft Bill. Following a concerted opposition effort mounted by several scientific and medical professional bodies of science and medicine during the consultation period on the Draft Bill, the RATE proposal was dropped from the final Bill that was introduced in Parliament in November 2007.

Almost a full year later, and four years after the initial review of human reproductive technologies and the law took place, the Human Fertilisation and Embryology Bill 2008 was passed by Parliament. It makes a range of amendments to the 1990 Act to take account of new scientific developments, to reflect changes in societal attitudes, and to update the HFEA's ability to regulate according to principles of better regulation (UK Government, 2008). Under the new Act, research utilizing embryos is permitted under the following criteria:

- a) increasing knowledge about serious disease or other serious medical conditions,
- b) developing treatments for serious disease or other serious medical conditions,

- c) increasing knowledge about the causes of any congenital disease or congenital medical condition,
- d) promoting advances in the treatment of infertility,
- e) increasing knowledge about the causes of miscarriage,
- f) developing more effective techniques of contraception,
- g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
- h) increasing knowledge about the development of embryos (2008).

Despite the comprehensive set of regulations applying to the derivation of hESCs, once the stem cell line has been created, any research conducted on it falls outside the regulatory authority of the HFEA. However, a condition of an HFEA research license to derive an embryonic stem cell line is that one must also commit to depositing the derived stem cell line in the national stem cell bank. An independent Steering Committee oversees the operations of the bank and all national research on embryonic stem cell lines. The bank provides stem cells to any company or institution that demonstrates the appropriate ethical, peer review and informed consent procedures are in place. Though there are no statutory regulations in place, there is an implicit expectation that individuals will adhere to the Code of Practice that is published (and regularly updated) by the UK Stem Cell Bank.

2.4 Conclusion

Like many new areas of science and technology, the scientific breakthroughs and potentials of embryonic stem cell research are not without controversy. We have shown how national conversations about hESC research began to take shape in the US and the UK almost 20 years prior to the publication of the Thomson and Gearhart papers. It is the nature and characterisations of these conversations and dialogues, the facts utilised and employed, the historical contingencies, the positioning against wider social dialogues, and the eventual conclusions (policy and regulatory outcomes) that are of interest to this doctoral study.

This chapter set out to describe the science of hESC research, the issues it raises, the policy history of embryo and hESC research in each country and the current mechanisms of oversight and regulation. What it has not done, however, is provided an analysis of how processes of governance are characterised and carried out in each

country. The following chapter will look to the theoretical literature to discuss what is meant by governance in the context of this research. After discussing the methodology of this thesis in Chapter 4, Chapter 5 will turn back to the processes of governance and their socio-political nature in relation to hESC research in the US and the UK. The discussion will build on the policy histories set out above, but will employ the concepts introduced in Chapter 3 as a theoretical lens on ‘good’ governance.

3. Governance of science and technology: Dimensions of analysis

3.1 *Introduction*

The previous chapter introduced the scientific background of human embryonic stem cells (hESCs) and its policy history in the US and the UK. It is a technology with a powerful therapeutic and scientific potential, but it is uncertain and unproven in many ways, with unknown biological and social consequences. It thus carries with it inherent and intractable elements of risk and uncertainty. These are more than risks and uncertainties associated with the technology itself, but extend to social, cultural and political arenas. With these come implications for the ways in which we deliberate on such risks in a society and make related policy choices (Fiorino, 1989, 1990; Fineberg et al., 1996; Pellizzoni, 2004).

Such implications are played out in examples such as the contrasting policy approaches of the US and UK in the area of hESC research described in the previous chapter. While the details of the different policies and regulations themselves are of interest, a singular focus on these specific policy and regulatory differences, as is often seen in the literature (Knowles, 2004), tells us about different mechanisms or instruments of government that might be used, and not about how we might deliberate and engage with them as a society. Each policy approach has developed for particular historical reasons and by different means in each country. It is precisely the development of these different policy approaches that serves to underscore the attention that might be paid to the processes behind the development, and indeed, the ways in which these processes have come about and interact with each other.

This idea is reinforced by the early work of Kooiman and colleagues who, in developing their concept of ‘social-political’ governance, point out that

the growing complexity, dynamics and diversity of our societies, as ‘caused by social, technological and scientific developments’, puts governing systems under such new challenges that new conceptions of governance are needed...Why not take them seriously and put them in the centre of new ways of thinking about how to govern, steer, manage, control and use them? (Kooiman, 1993, p 6).

This suggests a more holistic approach to analysis of this area is needed, one that looks at, and beyond, the institutions and instruments of government, to the wider social

processes and discourses that influence the development of governance itself. Indeed, it has been argued that the “entanglement of social, cultural, scientific and political values” in the biosciences raises challenges for a “new governance” that must acknowledge the cultural context of new technologies (Davies et al., 2003).

As a concept, ‘governance’ is used widely throughout various literatures ranging from political science to development studies. It is generally agreed to be a useful “organising framework for understanding changing processes of governing” (Stoker, 1998). But what is meant by ‘new governance’ in light of the entanglement in the biosciences, as suggested above, or ‘new conceptions of governance’ as suggested by Kooiman? It is clear that before we explore contrasting perspectives on governance, we must first unpack the term ‘governance’ itself. In doing so, we hope to illuminate the complex interplay of socio-political interactions and discourses that characterise decision-making processes in complex areas. In Section 3.2, we define what governance means in the context of this research and how it might be used in a comparative context. This discussion will be informed by a review of comparative policy studies as a means of gaining insights into overarching principles of comparison and theory. This will feed into a discussion in Section 3.3 of the wider literature on decision-making under conditions of risk and uncertainty. This is intended to bring us to an understanding of how governance might be affected under such conditions. The aim is to understand how governance in a context of risk and uncertainty is affected by, and might respond to, the challenges to ‘new governance’ raised by the biosciences.

3.2 Governance: Developing the concept

3.2.1 Overview

Governance is a very broad concept and is employed in various ways in the wider literature. A subset of this literature, sufficient to clarify how the term ‘governance’ will be used in this thesis, will first be reviewed in Sections 3.2.2 and 3.2.3. Section 3.2.4 will then discuss how governance might be thought of in a comparative context.

3.2.2 In search of a definition

It is difficult to find a standard, or commonly utilised definition of ‘governance’. Indeed, it seems the driving imperative for the introduction and use of the term is itself determined by the plurality of perspectives on the issues at hand. A ‘formal’ definition from the Oxford English Dictionary assigns the following primary (i.e., non-obsolete) definitions to the term governance: “1) ‘the action or manner of governing’; b) ‘controlling, directing, or regulating influence; control, sway, mastery’” (Oxford English Dictionary, 2009). This definition focuses attention first on the actions of governing, which tells us little about the substance of the term, but goes on to use words like ‘controlling’, ‘directing’ or ‘sway’ as means to assert influence over something. This is striking as the words can have apposite interpretations when used in conjunction with government actions. While the first two invoke images of direct government intervention, the latter implies a lighter touch.

Though a dictionary definition may seem a rather juvenile starting point for exploring governance, interestingly, the use of the term governance in the academic literature also employs both of the dictionary interpretations, as well as many more depending on the particular disciplinary tradition involved. Starting in the political science literature, Rhodes’ work *Understanding Governance* (1997) provides a comprehensive overview of the history and use of the term in studies of politics and government. He builds on a textbook definition of governance that is similar to the OED definition above, but introduces the notion of ‘*process*’ into the act of governing. He argues governance implies a “change in the meaning of government” where it refers to a “*new* process of governing; or a *changed* condition of ordered rule; or the *new* method by which society is governed” (Rhodes, 1997, p. 46). Though the introduction of notions such as ‘new’ and ‘process’ add layers and more nuanced meaning to our dictionary definition, Rhodes is correct in pointing out that there is confusion about what precisely is meant by the terms ‘process’, ‘condition’, ‘method’, or, we even argue, the term ‘new’.

At this point, it is helpful to look at the use of the term ‘government’ in comparison with governance. In the tradition of Anglo-American political theory, *government* is used to “refer to the formal and institutional processes which operate at the level of the nation state to maintain public order and facilitate collective action” (Stoker, 1998, p. 17). Here we see echoes of the stronger image of governance discussed above. In this sense, government is taken to imply a ‘top-down’ process of control

where, for example, behaviour might be regulated in specific ways in order to achieve specifically desired ends (Renn and Roco, 2006). By contrast, *governance* can be taken more broadly to imply a move from a ‘powers over’ perspective to a framework that grants ‘powers to’ institutions and people and aims for more enabling types of policy and regulation (Lyall and Tait, 2005). Others pick up on this and make explicit reference to the distinction that must be made between government and governance. While government can refer to a model of governing through coercion, governance focuses on the power of influence to accomplish specific governing ends (Murphy and Yanacopulos, 2005). As Stoker points out, it is “rather a matter of a difference in processes” (Stoker, 1998, p. 17). In other words, a difference between the means, but not the ends.

The literature reviewed so far is suggesting a move into a realm that focuses on the practices of governance. It is now becoming more clear what is meant by the earlier terms of process, condition, or method, and, moreover, why these are seen as distinctly ‘new’ in relation to older conceptions of government. These distinctions call attention to the role of diverse actors, citizens, and even individuals in the governance process, where there is an integration of multiple interests “into structures of action and political decision-making” (Gottweis, 2005). Using the concept of governance in this way can encourage us to look beyond state actors to the societal interactions that occur within the processes of governing. In this light, governance can be said to be about the “the sum of the many ways individuals and institutions, public and private, manage their common affairs”, including both “formal institutions and regimes empowered to enforce compliance as well as informal arrangements that people and institutions either have agreed or perceive to be in their interest” (Kazancigil, 1998, p 70). Here, governance is given substance and meaning through the references to both ‘formal institutions and regimes’, as well as ‘informal arrangements’ that might be entered into. Societal interactions are represented at multiple levels with reflection on their inherent diversity.

This use of governance in reference to a ‘social-political’ (Kooiman, 2003) or ‘social-cybernetic’ (Rhodes, 1996) system is perhaps best known through the work of Kooiman and colleagues in a collection of essays published in 1993 entitled *Modern Governance: New government-society interactions* (Kooiman, 1993) and further developed by Kooiman in later work (2003). When employed in this way, governance is taken to be the sum of a set of societal interactions that express the diversity, dynamics and complexity of the governing process itself (Kooiman, 2003). The concept draws

attention to “the patterns that emerge from governing activities of social, political and administrative actors” (Kooiman, 1993, p. 2) and highlights the role of interactions in this “two-way” traffic model (*ibid.*).

By stressing interactions in this way, Kooiman and colleagues arrive at a conception of governance that allows us to think about its utility as it applies to the issues of this thesis. Kooiman points out that when one is able to recognise the interdependencies of all the actors and their interactions, one sees that “no single actor, public or private, has all the knowledge and information required to solve complex, dynamic and diversified problems” (*ibid.*, p. 4). Policy problems are often complex and dynamic, but perhaps particularly so when we are considering technological and scientific advancements. This lends support to the observation that, when dealing with uncertain, and perhaps also controversial and contested, developments in science and technology, one must pay attention to the wider interactions amongst and between policies and politics, technologies and associated artefacts, discourses and social values, and the manifestations of all of these in the governance process (Stirling, 2008). Hence, with a clearer idea of what the term governance means, we can embark on a discussion of how governance can be used as an analytical tool, or ‘lens’, for addressing problems of governance facing society.

3.2.3 Governance as an analytical lens

We have shown that the term governance is used variously, and sometimes ambiguously. It can be expected, then, that different perspectives and uses of governance will emphasise different aspects of governing styles and the processes that emerge. Rhodes (1997) distinguishes six distinct uses of governance within the literature, including references to ‘the minimal state’, corporate governance, the ‘new’ public management, ‘good governance’, a socio-cybernetic system, and self-organising networks. These highlight, respectively, governance as characterised by a hands-off approach to the marketplace; the practices of corporate oversight; the use of private sector management methods in the public sector; efforts at government reform, especially in developing nation-states; the interactions of social and political actors; and the broader realm of public and private sector services. Each use is employed under different theoretical guises or analytical traditions. Similarly, state-centred perspectives on governance focus on the interactions of the state with other actors in crafting public policy (Smith, 2006), while a reflexive governance perspective explores the extent to

which governance is co-constructed and conditioned by previous institutional structures, social discourses or political manifestations (Voß and Kemp, 2006). Thus, regardless of the theoretical perspective or use, the point is that governance can be ordered or broken down, interpreted or analysed, employed or conceived of in many different ways, thereby leading to various implications for the study of the social, political or technological issues at hand.

In order to study these issues in a robust and systematic way, a range of typologies, modes, orders, or hierarchies of governance are employed in a wide variety of literatures to give structure and analytical consistency. In essence, each of these represents a different way of providing an analytical framework for either applying governance as a tool for problem-solving, or for enabling a deeper understanding of ‘governance’ as a theoretical concept. Inevitably, some frameworks prove more useful than others depending on the context within which they are applied. For example, Stoker (1998) uses governance to explore current dilemmas facing governments today and how they might be approached, while Kooiman (2003) offers a more theoretical exploration of the “utility of the governance concept as an instrument for conceptualising” key issues within society (*ibid.*, p. 8). These and other approaches will be investigated below in order to identify overarching principles that might be employed in the context of this research. We find that despite the varied levels of complexity in breaking down and applying the concept of governance to real-world analysis, each has a certain utility and contribution to make to our understanding of governance and its use in this thesis.

As alluded to above, Stoker develops a practical approach to governance by pointing out five central propositions for how we might think of and consider governance. The five propositions relate to different features of the governance process and are as follows: the set of institutions and actors that comprise the process; the blurring of formal and ‘traditional’ boundaries for societal and economic responsibilities; the power dependencies and relationships between institutions and actors; the autonomous and self-governing nature of networks of actors; and the secondary role of government in achieving collective change or accomplishing governing tasks (Stoker, 1998).

Stoker’s propositions draw our attention to several issues. His presentation of governance as an “analytical lens” illustrates the disconnect between the realities of decision-making and the normative codes used to justify traditional government roles. If

we recognise that there are complex sets of institutions and actors that operate within and outside government, then we are encouraged to accept the limitations of formal institutional perspectives on government as argued for earlier. This acceptance allows us to better understand and identify the multiple centres of influence and diverse links utilised between actors when appealing for legitimacy in political power. The picture becomes all the more complex when new actors emerge, when new governing challenges shake the foundations of the system (the economic crisis of 2008 being a particularly apt example here), or when new technologies and scientific trajectories are introduced into society. Thus, through Stoker's use of governance, we can gain an insight into critical issues facing government and governance systems, thereby providing new perspectives on how those issues might be addressed by practitioners and scholars alike.

While Stoker's use of governance is fairly straightforward, others have posited more complex dimensions and frameworks. Treib et al., (2007) aim to clarify the concept of governance by articulating different 'modes of governance'. They first identify three core dimensions of governance in the literature—politics, polity and policy—and then offer interpretations of governance under each of these dimensions. For example, under the politics dimension, governance focuses on the relationships between actors, while under the polity dimension, governance is a system of rules shaping the actors' actions. In contrast, governance under a policy dimension emphasises the role of 'political steering' and the instruments of policy making.

It seems to us that these dimensions of politics, polity and policy relate to elements of Stoker's propositions. If politics is about the relationships between actors, it directly corresponds to the actor relationships and power dependencies Stoker discusses. Polity relates to the formal rules that structure the actions of social actors, so the idea of power and control is reflected, especially the locus of authority that governs the behaviour of actors. The final dimension of policy relates to the actual instruments and mechanisms of governing. Thus, we find that two entirely different uses and conceptions of governance eventually can be seen as reinforcing each other.

Such mutual reinforcement of different authors presentations of governance is also found when we look at governance as a social-political set of interactions (as proposed by Kooiman and discussed above). In his theoretical development of this idea, most completely discussed in his widely cited work *Governing as Governance* (2003), he begins with the proposition that social-political interactions exist between the state,

market and civil society. The locus of each of these interactions is inherently diverse, dynamic and complex. Kooiman believes these types of interactions lie at the heart of every society. Thus, if governance is about collective problem solving and opportunity creation, then these interactions are where any analysis of governance must begin.

His framework for analysing governance is through the presentation of orders of governance. He argues that while first order governance places an “emphasis on governing as a process”, second-order governance gives attention to the “structural aspects of governing interactions, controlling or enabling problem-solving” (Kooiman, 2003, p. 153). The final order of governance can be found at a ‘meta’ level, where the focus is on the “continuous dynamic (re)construction of societal elements (diversity) in their interrelations (complexity)” (parantheses in original, Kooiman, 2003, p. 171). Through these orders, Kooiman illustrates how governance as a concept can be used as an instrument of analysis. In other words, he shows us how to make operational the abstract propositions, elements and dimensions discussed so far.

Importantly, Kooiman points out that the “creation and development of societal institutions are the result of historical ‘path-dependent’ processes” even though we see “institutional settings designed, created, maintained, reformed and even ended all the time” (Kooiman, 2003, p. 153). It implies that historical contingencies and path dependencies shape both how we currently define governance and how we attempt to change it. This insight will be important to bear in mind throughout this thesis as we explore how stakeholder perspectives on governance are constituted, and the variety of social, political, cultural and technological factors that impinge upon these perspectives and help to shape them.

At this point it can be reasonably argued that core elements of governance are emerging from the review of the theoretical governance literature presented above. First, there is a focus around the nature, type and extent of actor and institutional relationships, including the power dependencies that affect them. Second, the locus of government responsibility and control emerges as a central element important to analysing governance processes. Third, the mechanisms of governing are discussed, and, through these, the tangible realisation of the first two elements are borne out. As governance in the context of this thesis entails a focus on the process of collective social problem-solving, the first and the second elements appear to function as inputs to this process, helping to shape and define its trajectory. The third element is concerned with the practical work of putting the governance system into place. Drawing these elements

together, I will introduce here the idea that various ‘dimensions of governance’ can be developed from this analysis. These include: 1) processes and types of negotiation, engagement, and deliberation between society and the state; 2) the nature of institutional (de)centralisation; and 3) types of mechanisms used to govern. Attention to the reciprocal relationships between all three reflects the importance of Kooiman’s ideas about social-political contingency and interactions. These dimensions will play a foundational role in developing the methodological structure of the empirical component of this research and will thus feature prominently in the analysis and normative policy implications identified. They are introduced here, though, to accustom the reader to their use and language. A more thorough argument for them and their relevance to perspectives on good governance will be developed at the end of this chapter and over the course of the thesis.

The discussion thus far has taken us through some of the governance literature and has allowed us to arrive at a broader understanding of governance that will guide the theoretical development of this thesis. If we adopt a ‘social-political’ view on governance as described above, we are able to analyse observed differences in policies, regulatory regimes and collective social problem-solving in contested areas of the biosciences, such as hESC research. In this sense, ‘governance’ provides a lens through which to understand how perspectives on good governance develop and are constituted in wider society. Therefore, for this thesis governance is taken to refer to the *entire process* of defining, developing, engaging, deliberating, negotiating, establishing, implementing and reviewing the policy frameworks, regulatory structures, and other mechanisms of oversight for hESC research. These various processes can happen within and between many spheres, for example the public and private, scientific and political, ethical and practical, and moral and economic spheres. In other words, governance in this context is about the interactions between these multiple processes that are involved in governing hESC research. The question now becomes one of how to investigate these processes in a comparative context. To answer this, we will briefly consider some comparative policy approaches and their respective strengths and weaknesses in the context of analysing science and technology policy.

3.2.4 Governance in a comparative context

There is an enormous challenge in comparing processes of governance across nations in a way that enables progress and theory-building (Heidenheimer et al., 1990).

Comparative policy analysis began to emerge over the last few decades as a specific area of study to address this challenge (Leichter, 1979; Heidenheimer et al., 1990). The field has been defined in various ways, but the following is a useful starting point:

Comparative public policy is the study of how, why, and to what effect different governments pursue particular courses of action or inaction (Heidenheimer et al., 1990).

Within this statement, important parallels with the governance concepts described above can be found. The ‘how’ looks at the structure and processes of making government decisions, or specific mechanisms of governance. ‘Why’ might involve analysing the effect of historical contingencies, political cultures or actor relationships on change and evolution in government styles, hence a *new* form of governing processes. The notion of ‘to what effect’ underscores the consequences of these changing processes, or the normative implications associated with how governance ‘ought’ to occur. Thus, although this overview of the literature begins in the tradition of comparative policy studies, it is amenable to analysis under an organising framework of governance.

Recent developments in the field of comparative policy analysis make use of what might be thought of as ‘synthesis’ approaches (John, 1998) to explain policy variation and change. These incorporate aspects of traditional approaches into more holistic explanations of public policy variation that provide a guide for identifying important influences on the policy process as it evolves. For example, the policy advocacy coalition framework (ACF) (Sabatier, 1991; Sabatier and Jenkins-Smith, 1993) and policy network analysis (PNA) (Rhodes and Marsh, 1992; Marsh, 1998) both highlight the importance of inter-organisational alliances and relationships within policy sectors (John, 1998), but emphasise different aspects within these relationships when explaining policy change (Smith, 2000). Other approaches, such as Kingdon’s policy streams (Kingdon, 1995), look at the lifecycle of policies and treat the entire political system as a dynamic entity. Similarly, policy agenda studies give quantifiable “attention to the dynamics of how new ideas...may or may not be accepted in the political system” (Baumgartner et al., 2006).

What is most important about these approaches is the insights they provide into the mechanisms of policy configurations and inputs to policy interactions within the governance process. For example, the role of power in the PNA approach emphasises the importance of dependent relationships and hierarchies in a political process, while the ACF approach highlights the importance of competition between coalitions as a component of technical and policy-oriented learning. A policy agenda approach might

attribute governance differences to changing levels of national and political attention to an issue over time, highlighting the importance of historical contingencies. Each approach can, in theory, offer a distinctive explanation for different policy and regulatory configurations.

However, all of the approaches discussed so far are situated in a political science tradition that, while useful as an introduction for studies of comparative politics, does not explicitly take into account the unique influence of science and technology issues on policy making. In fact, for many years political science scholars discounted the need to compare technical, science-based policies because science was seen to be universal and beyond doubt (Jasanoff, 2005, p. 16-28; see also Banchoff, 2005). As this ‘Mertonian’ ideal of science started to be challenged, however, the field of science and technology studies (STS) branched out (Rip, 1999), and with that came fresh insights on comparative studies of science and technology policy (Jasanoff, 1997).

These insights from STS can acquaint us with the unique effects that cultural, political and scientific concepts may have on the ‘framing’ and ‘bounding’ of policy problems. This is particularly important for the socio-political lens on governance that has already been introduced. ‘Framing’ makes explicit the notion that particular cultural or social viewpoints on a policy issue cannot be discounted (Jasanoff, 2005), while ‘boundary making’ (Gieryn, 1983) is concerned with the way issues are presented as discrete objects with a particular set of ideological norms. Thus, the creation of politically significant ‘boundary objects’ (Star and Griesemer, 1989) has important ramifications as policy-makers, scientists or the public might try to relate to pre-existing framing assumptions, or to “ethical and social sensibilities concerning the products of biotechnology” (Jasanoff, 2005, p. 26).

Furthermore, awareness of the ‘social construction’ of technology and scientific facts has become increasingly important. Seminal works by Latour and Woolgar (1979) and Bijker (1995) introduced these ideas by showing that scientific practices, in addition to knowledge and progress, cannot be divorced from the particular socio-cultural situations in which they are developed and embedded.

As a social practice mediated through symbolic means, scientific knowledge emerges as a socio-technical construction set in specific historical and linguistic contexts of conjecture and refutation (Fischer, 1999, p. 301).

These situations not only affect how ideas come to dominate in a particular field, but also how the very practice of science can be affected by social and behavioural norms.

Many have shown how conducting studies from an STS or science studies perspective can provide fresh insights into studies of comparative policy. Abraham and colleagues (Abraham and Sheppard, 1999; Abraham and Reed, 2002; Abraham and Davis, 2005) focus on the role of science in the regulation of pharmaceutical drugs. They point out the effects of professional and disciplinary interests on the framing and presentation of the regulatory science itself, thus introducing a distinct sociological interpretation of regulatory actions in the US and UK. Parthasarathy uses a ‘co-productionist’ approach²¹, balancing the simultaneous interactions of science, technology and society, to demonstrate differences in the way genetic risk is defined and regulated in the US and the UK (Parthasarathy, 2004; 2005). Her finding that “national styles of politics not only lead to very different approaches to regulation, but also very specific understandings of our bodies and ourselves” (2004, p. 349) reinforces the reciprocal relationships of politics and policies, social and cultural influences, and boundaries and framing in our socio-political understanding of the governance process.

Though differences in governing structures across countries have been observed and analysed for STS issues, they are often conducted with a targeted focus on explaining specific policy outcomes or institutional structures. Observed differences are variously attributed to divergence in institutional structures (Bleiklie et al., p. 281), styles of regulatory decision-making (van Zwanenberg and Millstone, 2000), political cultures (Parthasarathy, 2004; 2005), national systems of innovation (Casper and Mataves, 2003), changes in global dynamics and policy ‘scenographies’ (Gottweis et al., 2009), or ‘civic epistemologies’ (Jasanoff, 2005). These attributions are significant and shed light on particular explanatory factors for different social and political problems arising from new technologies in the sciences. However, the authors do not always comment on the normative implications of their findings, that is, how best to address these problems in a governance context. Some have gone so far as to observe that in addition to neglecting state-level governance issues, there has also been more of an emphasis on “interpretive” rather than “explanatory” analysis in the STS tradition (Banchoff, 2005). For the purposes of this study, it will be important to draw out how these normative implications differ depending on whose (e.g. academic theorists) point of view they are coming from and at what level of governance (e.g. national or technological) the analysis is being conducted.

²¹ The term ‘co-production’ is discussed in detail by Jasanoff and other STS scholars in many works (see in particular, Jasanoff, 2004).

The next section will embed these views within the theoretical literature on decision-making under conditions of risk and uncertainty. It will discuss a variety of methodological, theoretical and practical insights which prompt us to think about the principles and analytical tools needed to understand how stakeholders in contested policy debates in the biosciences develop ideas about good governance. These insights, in turn, will help us to better understand how a governance lens can shed light on the processes of decision making in areas of complex technologies where goals and values are in conflict.

3.3 ‘Good governance’ in a context of scientific risk and uncertainty

3.3.1 Overview

New technologies may open up a realm of possibilities, but they bring with them new risks and uncertainties. This has led to the argument that certain policy problems are seemingly intractable, and conflicts between different values and belief systems may be irreconcilable (Pellizzoni, 2001). For example, hESC technologies may have the potential to treat incurable diseases, but this potential is unproven and the technology itself poses risks to individual and collective social values. Such contexts of risk and uncertainty must be considered in ways that address the scientific risks inherent in the new technology, and the associated social, cultural and moral risks. It is these latter components that pose particular challenges to governance in this area and create new imperatives for critically assessing the utility and insights provided by methods of risk analysis, science advisory processes, legislative practice, stakeholder engagement and public participation. However, in order to ensure legitimacy, this re-examination of processes of decision-making, and governance more widely, must be a collective one (Jasanoff, 2003). The question becomes one of how to both understand *and* effectively engage at political and social levels in these fundamental questions of decision-making under seemingly intractable conditions of risk and uncertainty.

However, the answer to this question lies not only in exploring its wider implications, but perhaps more fundamentally in making a crucial conceptual move within the theoretical framework of this thesis. We are concerned not only with the governance of hESC research, but specifically with *good* governance of hESC research. It is therefore critically important to move from the previous discussion regarding the

theoretical basis of governance, to a more normative one that looks specifically at the ways in which good governance is characterised within the literature.

In Section 3.3.2 we will first consider technological risk and the theories, insights and methods that have evolved to understand its implications. We will then discuss other approaches to decision-making that have been employed by governments in an effort to make complex decisions about science and technology, and the critiques that have been leveled at them. Moving from within the sphere of government institutions to the network of social and political actors that shape its workings, in Section 3.3.3 we will review the ways in which the literature presents ideas about the possible ways to engage the public and wider actor networks in governance processes. In an effort to reconcile the social and political spheres of governance, and to move us towards a more complete understanding of good governance, we will look at how best to answer the analytical and theoretical questions raised by this thesis. To do this, more recent insights from the theoretical literature will be employed to understand how the processes of governance may be conditioned by the interactions they promote.

3.3.2 Risk, uncertainty and technocratic governance

Risk and uncertainty

Regardless of the type of risk, it is accepted that conditions of risk and uncertainty pose considerable problems for rationalistic decision-making (Stirling, 2008). This is a perennial dilemma confronted equally in research governance, technology policy, and corporate strategy, and a range of methodologies exist for the express purpose of testing the robustness of decision-making in such cases. But what is meant by ‘risk’ in these contexts? What implications does this have for methods of decision-making, and how do they help address the problems of governance for contested technologies?

Interestingly, there is no shared or commonly accepted definition of the term ‘risk’ (Renn, 1998). A variety of academic, methodological and disciplinary traditions have distinct approaches to the concept of risk, and in many fields such as welfare economics (Arrow, 1970), anthropology (Douglas and Wildavsky, 1982), psychology (Slovic, 1987), and sociology (Fischhoff et al., 1984), risk analysis plays a central role. Fischhoff and colleagues argue that the definition of risk is inherently political (Fischhoff et al., 1984) and one that is affected by individual values and perceptions (Slovic, 1987). In his seminal work *The Risk Society*, Beck argues the concept of risk can only be

understood within the context of society's technologically driven process of modernisation. In this sense, risk is defined as the "systematic way of dealing with hazards and insecurities induced and introduced by modernization itself" (Beck, 1992, p. 21). Renn, in his review of three decades of risk research, points out that risk need not be a negative concept, and instead focuses on the causal effects of risk. In his view, "risks refer to the possibility that human actions or events lead to consequences that affect aspects of what humans value" (Renn, 1998, p. 51). Though it could also be argued that natural risks would fit into this category, the point is that risk can exhibit both descriptive and normative characteristics. This allows one to account for more subjective, cultural and context-dependent situations that may affect the way risk is handled and thought of by the public and policy-makers alike.

While these social science influenced definitions are more widely accepted today, for many years the dominant risk analysis methods reflected the origin of the concept of risk in the insurance and decision science fields (Starr, 1969). Technical approaches to risk assessment dominated, where quantitative methods attempt to measure, in numerical terms, the likelihood of different hazards and the ways to mitigate them. The methods ranged from cost-benefit analyses, life cycle assessments, decision analysis, "technical perspectives" (including actuarial, environmental and technological analyses) (Renn, 1998), and multi-criteria approaches (DTLR, 2001). These methods are largely quantitative in nature with "magnitudes and likelihoods held to be readily characterized on a cardinal numerical scale", holding in common "a tendency to treat the concept of risk, at least in principle, as an objectively determinate quantity" (Stirling, 2003, p. 36-37). It is not hard to see why this concept of risk assessment as a strictly quantitative, measurable entity appealed to policy-makers. The variables that require consideration when assessing risk in a decision-making context are diverse and complex (see, for example, Collingridge, 1980) and often leave those responsible for the decisions struggling with the various options. Thus, when faced with policy issues that hold a large degree of uncertainty and whose impacts, whether positive or negative, concern public safety, health or economic growth, it is far easier to justify decisions with numerical answers based on lives saved or money earned.

Perspectives from the social sciences, including sociology, anthropology, psychology and science and technology studies have raised serious criticisms against the use of such technical risk assessment methods. They have pointed out that quantitative approaches are not as objective or value-free as they might appear to be, if

at all. Early contributions from Fischhoff and colleagues pointed out that interactions between human activities and their consequences are far more complex than the average probabilities used in technical risk analyses are able to reflect (Fischhoff et al., 1984). Moreover, values are inextricably linked to every part of the risk analysis process, from characterisation to interpretation (Fischhoff, 1995), a finding that calls into question the claim that analysts of risk are themselves objective, much less the methods themselves. Others have made a related point when arguing that technical approaches to risk fail to account for differences in how, for example, the concept of ‘magnitude’ can be conceived differently by different parties (Stirling, 1998, 2003; Renn, 1998, p. 53).

In addition to problems with the techniques of risk assessment, a related, but distinct strand of critical work emphasises the sociological perspectives on risk. Attention is drawn to the processes of social learning and social construction that affect individual and collective definitions of risk (Renn, 1998). Insights as to how the interactions between society and the technologies introduced into them structure and condition perceptions of risk are particularly important. They highlight the need to account for the social construction of risk in decision-making (Renn et al., 1993) by developing new methods that take this into account. The point to note here is that the risks associated with any policy choice will take the form of many related, but distinct issues, and the value judgements placed on each will vary according to different parties. Moreover, the ways in which people perceive of a risk as ‘hazardous’ or ‘harmful’ will also vary by individual (Dietz et al., 1996, cited in Renn, 1998). Thus, failure to consider the wider social and cultural interactions can undermine the legitimacy of the whole risk analysis process, serving

to render less visible the fundamental social questions embedded in the very design of technological research. By underplaying the questions of health or social consequences, they [risk analysis methods] hide the basic normative questions essential to democratic decision-making in the mystique of statistics (Fischer, 1999, p. 297).

Each of these critiques serves to underscore the fundamental conditions of ignorance and ambiguity, as well as risk and uncertainty, that are ever-present when considering what, precisely, our knowledge is in relation to the likelihoods and possible outcomes of risk. Such “dimensions of incertitude” (Stirling, 1998; 2003) encompass many of the insights from the social sciences on the assessment of risk and show that these insights do not just amount to footnotes or theoretical musings, but have real practical implications for our treatment of risk in a decision-making context. For

example, the true comparability of risk metrics across different circumstances (for example, mortality metrics) has been questioned, as has the ability to develop comparable metrics or decision tools under conditions of uncertainty (Collingridge, 1980). When conditions of ambiguity and ignorance are added into the mix, further complexities abound. Ambiguity is concerned with the variety of framing assumptions that might be applied to a set of possible outcomes, which necessarily hinge on a range of social values, while ignorance is a state of ‘unknown unknowns’, where one cannot even fully characterise the parameters of the problem.

Though critiques of formal risk assessment methodologies began in the 1970s, and in some cases earlier (see Slovic, 1987, for a review in the area of risk perception), evidence was not seen of the uptake of the ideas into policy circles until the mid-1990s. In 1996, it appeared that the US government was beginning to understand and recognise the need to account for social and cultural influences in the process of risk analysis, as well as the need for more participatory approaches to assessing, managing and communicating risk (Fineberg et al., 1996).²² These insights not only relate to the need to think about risk assessment in new ways, but also the ways in which experts themselves should contribute to decision-making processes in areas of technical risk and uncertainty. Slovic observed (albeit almost a decade before the publication of Fineberg’s work) that “risk communication and risk management efforts are destined to fail unless they are structured as a two-way process. Each side, expert and public, has something to contribute” (Slovic, 1987, p. 285). The concept of ‘expert’ in this quote suggests we might take a closer look at a less overt, but nonetheless important, component of technical risk assessment: the contributions of expert advisory committees. These bodies are set up to advise on the scientific and technical data involved in policy decision-making, and, hence, risk analysis processes. However, as we have shown the case to be with the methods themselves, technocratic advice has serious short-comings.

Technocratic expertise

Policy-makers have often relied heavily on expert-based, technical inputs to decision-making, leading some to observe that “there has been a universal assumption (however superficial and laced with cynicism) that scientific expertise is the crucial

²² Fishhoff (1995) points out that Vice-President Gore’s White Paper *Reinventing Government* also recognised that quantitative risk assessments needed to be clarified in terms of their uncertainty and inherent subjectivities.

component of decision making, whether concerning Nature or society” (Funtowicz and Ravetz, 1993, p. 741). Much of this is based on the belief that the pursuit of scientific truth is itself an entirely objective, empirically driven process (Polyani, 1962). In the face of polarised politics, science seems to offer a neutral middle ground that could be used to “de-politicise public issues” (Nelkin, 1975, p. 36). The so-called “dilemma of expertise” has been around since the days of Plato and Socrates (Nowotny, 2003), but it has not become any clearer how best to employ expert advice in processes of decision-making. Much the same as in the field of risk assessment, many have called the objective role of science into question. They argue that not only is the pursuit of scientific progress a socially constructed phenomenon (Latour, 1983), but that science itself can offer multiple answers to the same question (Collingridge, 1980; Collingridge and Reeve, 1986).

As Jasanoff has pointed out, the use of expert committees became especially prevalent in the United States in the 1960s and 1970s. However, as their strength in numbers grew, so did concerns that expert committees were rapidly becoming a ‘fifth’ arm of the US government (Jasanoff, 1990). As an abstract notion, this may merely raise eyebrows, but it becomes more troubling when coupled with the realisation that, just as technical risk assessments are affected by different value judgements, social constructions, or framing assumptions, so too is the scientific ‘evidence’ used to feed into risk analysis and other types of decision-making. Whether the medium is a technical risk assessment or a panel of expert deliberators, the influences and outcomes are still the same, leading Millstone and van Zwanenberg to note, “it is not possible to construct a risk assessment from available scientific data without embedding it in some prior, socially derived framing assumptions” (2001, p. 101).

In terms of the practical implications of such a so-called ‘politics of expertise’, Fischer has contributed considerable empirical and theoretical work in this area, especially in combining insights from the political science literature with ideas about expert-based decision-making (Fischer, 1990, 1993, 2003). He argues that in today’s postindustrial societies, science and technology are central to economic growth. Policy-makers realise this and are often faced with competing priorities and policy goals. In this context, “governance devolves to a consideration of what is feasible”, and technocracy itself comes to refer “to the adaptation of expertise to the tasks of governance. It gives rise to a theory of governmental decision-making designed to promote technical solutions to political problems” (Fischer, 1990, p. 16-18). The

problem with this lies in the realisation that such ‘technical solutions’ become the preferred manner of side-stepping the complex social and political problems posed by rapid technological advancement. Nowotny and colleagues echo this argument by positing that although expertise can provide reliable knowledge, it perhaps does not provide “socially robust knowledge” that captures the wide range of culturally specific, locally contingent, and publicly deliberated ‘knowledges’ that exist in technical and scientific policy debates (Nowotny et al., 2001; Nowotny, 2003). The idea is that we should move towards a more “pluralistic expertise” that captures the variety of knowledge types that impinge upon the debate.

In these arguments, we can see theory and practice moving closer to responding to the demands for greater accountability and legitimacy that are invoked when academics and the public alike call for a greater “democratisation of expertise” (Nowotny, 2003) in decision-making and governance processes. Thus, throughout this discussion of quantitative and qualitative models, inputs and approaches to risk assessment and technocratic decision-making, several themes begin to emerge. Terms like ‘accountability’, ‘legitimacy’, ‘trust’, ‘local knowledge’, ‘social values’, ‘lay perspectives’ and many more are all invoked in various ways. Taken individually, they are intended to inform ways in which, for example, risk assessment techniques might be made more reflective or expertise more democratic. Taken as a whole, they make clear the normative principles that can inform the discussion of how good governance might operate under conditions of risk and uncertainty.

As Beck’s theory of reflexive modernisation has shown us, we live in a society characterised by the continued proliferation of risk and uncertainty. New technologies carry with them significant unknowns and it is our job as a society to participate in policy-making processes as we collectively consider the best ways to deal with them. Singular approaches that employ only technical, quantitative answers fall short, as do purely expert-based approaches as they fail to include the more ‘social’ dimensions that are needed. In this context, the problem posed to the governance of science, and particularly *good* governance of science, is how to put into practice such methods and ideas. There is a need for ‘technologies of humility’ in decision analysis that will

make apparent the possibility of unforeseen consequences; make explicit the normative that lurks within the technical; and acknowledge from the start the need for plural viewpoints and collective learning (Jasanoff, 2003, p. 240).

With this in mind, attention now shifts to the deliberative turn in studies of government and decision-making and the ways in which public engagement can, or should according to many normative perspectives, influence wider governance processes.

3.3.3 Deliberative democracy and public engagement

In a widely cited, early contribution to the literature on risk and democratic decision-making, Fiorino points out that

Entirely new fields like genetic engineering pose substantial scientific uncertainties where a political consensus has not even begun to emerge. Affected publics demand a role in technically based decision making, while administrators grope for ways to involve them constructively... A major question is whether democratic institutions and processes can keep pace with these changes (1989, p. 501).

This nicely encapsulates many of the issues that are raised by the advances in the biosciences, where risk and uncertainty prevail as conditions under which decisions must be made. In response to criticisms of technocratic and quantitative risk analysis approaches as described above, calls like Fiorino's have been made from a variety of places for more qualitative, participatory and deliberative methods of decision-making. These are proposed as a way to ensure the cultural and social implications of new technologies and policy decisions are taken into account. A widely acknowledged definition of deliberation in this sense comes from the US, where the National Research Council defined deliberation as

any formal or informal process for communication and collective consideration of issues. Participants in deliberation discuss, ponder, exchange observations and views, reflect upon information and judgements concerning matters of mutual interest and attempt to persuade each other (Fineberg et al., 1996, p. 73).

Thus, deliberation refers to the “discourses in which political debate is conducted, together with their limits and achievements” (Jasanoff, 2005, p. 285) and can be linked to the governance concern with the characterisations of socio-political interactions.

Central to discussions about participation and deliberation is a concern with the democratic legitimacy of policy-making in the absence of public input and engagement. Much of the theoretical foundations in this area come from the work of Habermas and discussions of the principles of democratic decision-making and engagement (Habermas, 1975). Building on this, early participatory theorists claim that “participation engenders civic competence by building democratic skills, overcoming feelings of powerlessness and alienation, and contributing to the legitimacy of the political system” (Fiorino, 1989, p. 536). The aim of deliberation and participation is

thus similar to those discussed earlier: to increase legitimacy and trust in the conduct of democratic decision-making. It includes the idea of ‘participatory policy analysis’ (Fischer, 1993) that seeks to “open the process to a wider range of interests and concerns” and to “integrate more fully the normative aspects of the inquiry process” (Fischer, 1999, p. 300). In doing so, it thereby allows for the incorporation of social values in the policy development process (as discussed in Pelletier et al., 1999), a feature sorely lacking in the quantitative and technocratic techniques discussed above. The term ‘deliberative democracy’ has been coined as a wide-ranging reference to many of these ideas. It is defined as a process that refers to “the idea that legitimate lawmaking issues from the public deliberation of citizens. As a normative account of legitimacy, deliberative democracy evokes ideals of rational legislation, participatory politics, and civic self-governance” (Bohman and Rehg, 1997, p. iv).

Specific methods for achieving such democratic aims are wide-ranging. Public deliberation exercises held at local, regional or national levels are one such example of these efforts and can include citizens’ juries, public hearings, consensus conferences, and focus groups that elicit a range of views on an issue (Rowe and Frewer, 2005). Each method can help achieve different goals, but it is precisely this point that serves to underscore the different aims that each method seeks to foster. Consensus conferences help participants to reach a consensus on a given issue, while focus groups elicit a range of views and facilitate discussion and deliberation. The question becomes one of determining how to most effectively address the risks inherent in today’s technologically advanced societies (that is, in a way that minimises potential harm to society), while still allowing for the views of the general public to be heard and considered, even when their inclusion might pose political and institutional difficulties. The aims of such qualitative and ‘participatory’ approaches “should be broader than the instrumental objectives of the agency or key clientele groups. Its ethical basis should reflect democratic values and the intellectual contributions of democratic theory, not just the need to satisfy opposition demands as they arise” (Fiorino, 1989, p. 546).

Pellizzoni’s work on processes of deliberative decision-making offers an additional take on how participatory deliberations might play out in a policy debate where irreconcilable values dominate (Pellizzoni, 2001, 2003). Like others, he points to the shortcomings of expert-based approaches to policy development, stating that

the debate on deliberative democracy has been undoubtedly stimulated by the inadequacy of strategic or elitist approaches to an increasing number of [policy] problems characterised by extreme complexity (Pellizzoni, 2004, p. 60).

However, he questions Habermas' claim that it is through deliberation and democratic process that every problem can find a solution. For Pellizzoni, some conflicts are intractable and values are in irresolvable conflict. Faced with situations where there is no "universal reason", he argues we must look beyond traditional democratic processes and deliberation to the motivations and cognitive aims behind the decision-making process itself. In other words, when values are inextricably intertwined with the policy debate, we must be more attuned to the motivations of policy actors and their strategies for engagement in participatory process.

In a much expanded discussion on such motivations, Stirling offers a subtle, yet important distinction in analytical starting point (Stirling, 2008). He argues that rather than singularly focussing on the differences in participatory approaches to appraisal as opposed to technocratic ones, we might find more useful analysis in considering the motivations for engagement as revealed in different appraisal strategies. Building on the work of Fiorino and others, (Fiorino, 1989; Fineberg et al., 1996), Stirling has argued that we might consider the implications of different normative, instrumental or substantive imperatives for engagement in different types of participatory or expert appraisal exercises. These imperatives can be used to explain stakeholders' motivations for participating in engagement exercises, or to examine the intentionality behind different analytical or participatory approaches to policy appraisal. Thus, these imperatives can affect the way in which stakeholders engage in the participatory or appraisal process, as well as having effects on the strategic choice of appraisal processes in the first place. The questions below thus take centre stage:

Are there commonalities, synergies, or tensions transcending the apparently simple dichotomy [between expert analysis and participation exercises]? Are there conditions under which specific expert-analytic processes might potentially be more conducive to enhanced social agency or (conversely) particular participatory procedures less so? (Stirling, 2008, p. 268)

If we address each in turn, *normative* imperatives manifest themselves in a variety of ways, but they are all concerned with the processes (rather than outcomes) of appraisal (Pellizzoni, 2003). In this sense, appraisal strategies are designed with a concern for embodying normative, democratic principles and being the 'right thing to do', with little concern for specific ends being achieved. Under normative democratic perspectives, the process of evaluation or appraisal is one that might, alternatively: invoke "the scope, resourcing, openness, representativeness, accessibility, facilitation, transparency, or accountability of engagement"; hinge on "capacities for social

empowerment”; and be a “self-evidently good thing” (Stirling, 2008, p. 269). By contrast, *instrumental* imperatives are characterised by a considered (and often considerable) interest in the outcomes of appraisal or evaluation processes (Pellizzoni, 2001). Thus, appraisals designed from an instrumental perspective are concerned with “efficacy in realizing particular favored ends. The grounds for favoring such ends are simply assumed... Efforts thus concentrate on the interests of specific constituencies, institutions, or technological systems, irrespective of wider normative values” (Stirling, 2008, p. 269).

Finally, *substantive* imperatives are also concerned with the outcomes of the appraisal, but not in the way instrumental imperatives are in terms of particular “values and ends”. Instead, substantive imperatives have a “focus on explicit, socially deliberated, publicly reasoned evaluative criteria for the outcomes themselves” (Stirling, 2008, p. 271). Early evidence to support this interpretation can be found in the work of Fiorino, who argues that though the participation movements of the 1960s and 1970s promoted “substantive democratic values” and discussion about what public participation in the democratic process would mean and could achieve for society, it “did very little to promote the procedural ends of democracy ... It substituted litigation for discussion, joint problem-solving, and a search for common ground” (Fiorino, 1989, p. 504). In other words, appraisal processes might be designed in order to facilitate wider discussion about the quality of desired outcomes and how that quality might come to be agreed on and judged. Thus, while adding a critical layer to the analysis of the deployment and use of public participation methods, these three imperatives may also have important explanatory power in understanding how and why perspectives on good governance differ amongst stakeholders in the hESC research debate.

Insights such as these which call into question the imperatives behind different engagement methods, are not necessarily attempting to pass judgement on which means lead to normatively ‘better’ ends. The point is merely to show that though public engagement or deliberative exercises might allow for a plurality of views to be expressed in a way technical assessments cannot reflect, once unpacked they may be as equally subject to human agency, contending framings, implicit agendas or hidden assumptions (Stirling, 2008). Rayner points out that though participatory methods have potential, their use in the social science literature, or even employed in policy circles, are subject to irreconcilable “political-cultural” constraints (Rayner, 2003). Thus,

qualitative methods may just as easily serve to ‘close down’ decision-making processes and policy trajectories towards particularly desired ends.

This may appear to be a dilemma with no way out. Traditional approaches to risk assessment have been shown by the social sciences to be unsatisfactory, but equally, new qualitative and participatory approaches can mask hidden agendas and instrumental shaping of policy choices. How can these be reconciled? Returning to the challenges discussed at the beginning of this chapter, scientific progress today is rapid and there are, often unknown, societal implications. Funtowicz and Ravetz term this a situation of ‘post-normal science’, where although science and its future implications are characterised by uncertainty, these uncertainties are embraced and “not banished, but managed, and values are not presupposed but are made explicit” (Funtowicz and Ravetz, 1993, p. 740). Under these conditions, we must look anew at processes of decision-making and engagement. Analysis should emphasise the diversity, complexity and dynamism of social-political interactions and their effect on the processes of government. Similarly, analysis of *good* governance must give consideration to how policy decisions can be made in such a way that acknowledges and makes explicit the culturally contingent, uncertain and risky context of hESC research, in particular, and science and technology more generally.

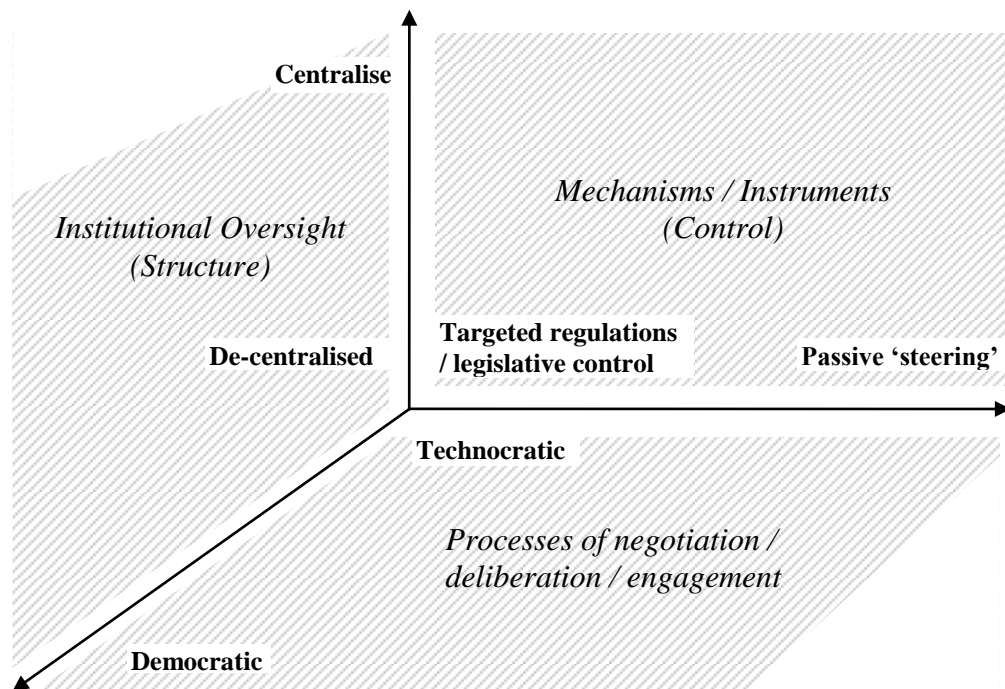
3.4 Conclusion: Dimensions of governance

A challenge of this research is to not only distinguish what is meant by good governance, but also to analyse whether distinct and discernible perspectives on this concept exist amongst different groups of stakeholders in the UK and the US. Overcoming this challenge will depend, in part, on our ability to address this in a robust and systematic way. Just as we have now seen how the governance literature has developed systematic ‘lenses’, ‘modes’, ‘orders’ or ‘hierarchies’ which contribute to theoretical development, so we too must identify an organisational framework that can both draw together the theoretical strands identified above, but also inform and structure the research approach. This approach must not only address core elements of governance drawn from the literature above, but it must also incorporate important theoretical and empirical insights from STS in relation to ‘good’ governance.

Particularly relevant to this discussion, then, are the ideas introduced above that can acquaint us with the unique effects that cultural, political and scientific concepts can

have on the ‘framing’ and ‘bounding’ of policy problems. In particular, these insights can be used to flesh out the dimensions of governance introduced earlier. These can now be described in a more concrete way with implications of ‘good’ governance explained for each axis. That is, within each dimension, various perspectives on what qualifies as ‘good’ may exist. While it is these perspectives are explored through the empirical methodology of this thesis, it is important to ground the basis of this methodology in the theoretical ideas about governance, and especially *good* governance presented above. Therefore, to sum up, the dimensions are: 1) the nature of institutional centralisation, 2) the processes and types of negotiation, engagement, and deliberation between society and the state, and 3) the types of mechanisms used to govern. A brief description of each dimension follows the schematic drawing below.

Figure 3.1: Schematic representation of dimensions of good governance



The first dimension, institutional oversight, refers to the institutional structure and locus of authority that is used to govern a biomedical research programme. Within the political science literature, the study of institutions, or institutionalism, has a specific meaning and analytical approach associated with it. Institutions are defined as the “formal rules, compliance procedures, both formal and conventional, that bind the components of the state together and structure its relationship with society” (Hall, 1986; cited in, Gottweis, 1998, p 14). However, this is not the way in which it is used here,

although we do draw on the notion by identifying the locations of formal rules and procedures as either ‘centralised’ or ‘decentralised’.

Our use of institutional oversight as a dimension of governance acknowledges the importance of identifying a locus of decision-making and formal authority within a given governance structure. This may also inherently reflect the overall structure of the country, for example, a federal or unitary state. In addition, some governance structures may have both centralised and de-centralised elements. It will be important to be able to reflect these aspects and their impact, if any, on the perceived ability of the governance system to function appropriately (however this may be defined).

The second dimension, mechanisms/instruments of control, relates to the regulatory environment and the mechanisms or instruments of government that are used to maintain and shape that environment. Juxtaposed on this axis are targeted regulations and passive steering mechanisms. The latter might include market-based mechanisms of professional self-regulation or federal funding guidelines. Targeted regulations include legislative acts, laws or regulatory statutes that may set boundaries and impose restrictions on how research can be conducted or therapies developed. The extent to which one instrument is preferred over another may reflect particular views on, for example, the nature of scientific autonomy and its relationship with government, itself.

The third dimension is about the processes of deliberation, negotiation and social engagement that may lead to the emergence of new governance systems or policy decisions. The poles of this dimension are characterised as either technocratic or democratic. As has been discussed throughout this chapter, the former may include expert-based, scientific procedures involving quantitative analysis, technical inputs and solicited advice from expert advisory panels. It is characterised by the science-led model of expert inputs to policy-making. The latter addresses the recent trend seen in the rise of democratic and participatory methods of discourse, where citizens and non-experts are brought into the process to establish a lay perspective in decision-making.

These three dimensions will form the basis of the empirical methodology presented in the following chapter. We have now established the scientific background of hESC research, reviewed the policy histories in the US and the UK, explored the theoretical foundation of governance, and introduced implied bases of ‘good’ governance within the academic literature. We will now move to the heart of this thesis and a discussion of how all of these components will be analysed through a two-part methodological research strategy.

4. Methodology: An introduction to Multicriteria Mapping

4.1 *Introduction*

The previous two chapters provided the contextual and theoretical foundation for this thesis. We must now consider how to use these foundations to explore the primary research question regarding the ways in which perspectives on ‘good’ governance are constituted among different groups of stakeholders in the US and the UK. Two independent sources of evidence are used to compare and analyse these perspectives. These arise through *i*) a literature-based review of policy documentation and *ii*) direct elicitation from specialist experts and representatives of key stakeholder groups. In light of the theoretical aspects of governance outlined in the previous chapter, it is of particular importance that the elicitation methodology be one that can systematically and reflexively elicit notions of good governance in a way that retains accountability and transparency.

This chapter will first introduce the case study strategy employed in this thesis and justify the chosen countries and technology of study. It will then review each methodological approach in relation to the two independent sources of empirical evidence. The chapter will necessarily focus more on the novel methodological process of eliciting and analysing stakeholders’ perspectives, entitled Multicriteria Mapping (MCM). We will first justify the selection of MCM before describing the elicitation and analysis in detail in Sections 4.3-4.5.

4.2 *Case study selection and methodological framework*

4.2.1 Overview

This research combines a case study approach with a particular elicitation methodology. According to Yin, a case study is “an empirical inquiry that *i*) investigates a contemporary phenomenon within its real-life context, especially when, *ii*) the boundaries between phenomenon and context are not clearly evident” (Yin, 2003, p. 13). They are most useful for exploring research questions of ‘how’ and ‘why’ when the researcher does not want, or does not need, to control the behaviour of participants or

research subjects and when the events being studied are contemporary, as opposed to historical (Yin, 2003, p. 5-9). Multiple methods can be used in a case study to explore a given research question and the findings arising from such independent methods can usefully be triangulated. Thus, the two-pronged approach to the research strategy was adopted, with a literature-based review of policy documentation and a direct elicitation methodology with key specialists in the field of hESC research, in order to provide two empirical bases for comparison. Such relative flexibility in the types of methods employed are an advantage when time and resources are limited. This was the case in this doctoral research study and early on a decision was made to limit the study to only two countries and one technology due to existing resource limitations. We will first briefly justify the case study selection in the chosen countries – the US and the UK – and technology – human embryonic stem cells, before moving on to discuss the literature review and elicitation methods in turn.

4.2.2 Case study selection

Human embryonic stem cell research was selected as the case study technology for reasons that build on the overarching theoretical ideas discussed in the previous chapter. That is, the technological area of study needs to be one where governance stakes are high, future applications uncertain, assumptions varied and conditions unknown. It must be one in which risk and uncertainty exist not just from a scientific or technological standpoint, but from a cultural and social one, as well. This is necessary if we are to understand perspectives on good governance in such a way that allows us to explore wider implications for socio-political governance. In other words, the aim is to look beyond the institutions and instruments of *government* to the wider social and political *processes* and *interactions* which characterise *governance*.

On the basis of the above, the selection of a case study technology was guided, in part, by the following criteria:

- *the chosen area of research or technology must be at similar levels of development in different countries;*
- *the chosen area of research or technology must be politically and socially salient in various national settings; and*
- *the chosen area of research or technology must lend itself to sufficiently different perspectives on good governance amongst a variety of policy actors in a variety of national settings.*

For reasons that are apparent in the scientific review in Chapter 2, hESC research fulfils all of these criteria. It is ‘global’ in the sense that the capabilities and capacities for conducting the research are present in several countries around the world. Though it is politically and socially salient in a variety of national settings, there are still important differences in the ways in which the research *comes to be salient* and the specific differences in culture and national context thereby reflected. The myriad of US state laws that have been passed in relation to embryo and hESC research reflect the diversity of views that can exist within one nation, let alone between nations. Our attention now turns to the selection of the two countries within which this variation might be compared.

The policy histories described in Chapter 2 substantiate the observation that differences in policy exist between the UK and the US for hESC research. This suggests that ‘sufficiently different’ perspectives on good governance may also exist in each country. However, this observation alone is not enough to justify the selection of these two countries as the case study locations. The criteria used for this selection have different emphases to those above, given they are concerned with the *location* of the case studies as opposed to the *topic*. Thus, in each case study country the following conditions should be satisfied:

- *similar political structures should exist (e.g. Western democracies);*
- *hESC research should be at a similar level of scientific development;*
- *hESC research should be politically and socially salient;*
- *hESC research and associated governance considerations should inspire active, diverse and sophisticated civil society discussions; and*
- *hESC research and associated governance considerations should raise, as a result of the civil society discussions and other interactions, sufficiently different notions of good governance.*

Since the policy histories of each country were discussed earlier, we should be able to understand how the UK and the US fulfil these criteria. Though each country has different policy and regulatory frameworks, the science is sufficiently advanced in each country and both are arguably at the forefront of the field. The policy histories reviewed in Chapter 2 show embryo research, and more recently hESC research, has been a socially and politically salient issue for more than thirty years. The discussions in the UK and the US have been active, diverse and sophisticated over this time, beginning with debate over the permissibility of embryo and foetal tissue research and continuing through to the present state of embryonic stem cell research.

In addition to these more theoretically grounded selection criteria, the two countries were also selected for reasons of feasibility. The author is located in the UK, and so travel for interviews and access to information in the UK were both straightforward. The author conducted MSc research on the topic of hESC research policy in the US, and so had a ready network of contacts which could be mobilised there. The next section discusses the method employed to analyse the first source of independent evidence: the policy literature.

4.2.3 Policy literature analysis

A policy literature analysis is central to the research strategy of this thesis as it not only informs the wider context in which the research is occurring, but it also provides the basis for one strand of the empirical findings. As could be seen in Chapter 2, the policy literature on the two case studies is a vast dataset in itself. In this research, the policy documents will be used for two main purposes. First, a wide-ranging review is used to contextualise the issue and inform the elicitation methodology through the identification of, for example, the main policy and institutional actors in the debate, the distinct viewpoints held by those groups, and the different governance scenarios in countries around the world.

Second, a subset of the formal policy literature is analysed as an independent source of evidence in order to discern whether perspectives on good governance emerge from the policy literature and, if so, in what ways. Thus, inductive reasoning is used to provide the basis of comparison for the deductive component of the research, i.e., the stakeholder interviews. This provides a ‘baseline’ that is independent from the elicited stakeholder views and thereby provides a critical reference point.

In order to be confident in the ‘baseline’ of perspectives emerging from the policy literature, the review itself must be conducted in a robust fashion. Though a full-scale content analysis (Krippendorff, 2004) is beyond the scope of this thesis, and, moreover, is not necessarily called for by a research strategy employing mixed methods (Smith, 1996), the literature review was conducted using basic principles of content analysis. Content analysis is, at its simplest, “a systematic analysis of texts” (Krippendorff, 2004, p. 3). It is further elaborated as “a method by which we may summarise fairly rigorously certain direct physical evidences of the behaviours of, and the relationships between, various types of political actors” (Manheim and Rich, 1995, p. 184-185). Conducting a full content analysis, then, is a systematic undertaking, that

requires (at least): *i*) the definition of a population of texts or communication records; *ii*) the establishment of a ‘dictionary’ set of criteria for coding; *iii*) the determination of a unit of measure; and *iv*) the establishment of several ‘coders’ to work with the texts and reduce potential bias.

The modified content analysis approach employed in the review of the policy literature addresses, to a small extent, each of these four points. A population of texts was defined through the identification of policy documents that were ‘formally’ produced by governments or government-sponsored entities in the UK and the US. Initially, 12 possible texts were identified before the final selection of six policy documents (three in each country). This selection process is reviewed in greater detail in the following chapter.²³ Analysis of the six chosen texts was conducted in an iterative fashion which allowed for themes of good governance to emerge through systematic analysis according to: *i*) organisational structure, *ii*) content in terms of issues addressed and *iii*) relevance to governance according to social, political and scientific themes. In relation to this latter point, as they emerged, themes of good governance²⁴ were further used to categorise and ‘code’ sections of text according to their thematic relevance. The findings were recorded in such a way as to allow for relative determinations of coverage according to each theme and within each text to be identified.²⁵ Thus, though the procedure did not amount to a full content analysis, it did comply with underlying principles concerning use of ‘criteria’ and ‘codes’ by the analyst.

Having now described the basis for the first source of evidence used in this thesis, we will turn our attention to the second, methodologically independent, source of evidence: stakeholder interviews. Before describing the interview elicitation process, we will discuss the theoretical basis on which an appropriate elicitation methodology was selected.

4.3 Selection of an elicitation methodology

4.3.1 Overview

Various methodologies exist for the social appraisal of contending regulatory or policy interventions. As discussed in the previous chapter, technically based risk

²³ See the discussion in Chapter 5, p. 94-99.

²⁴ While it is not necessary to identify these themes here, it is important to justify the way in which they were identified and preview their centrality to the empirical analysis.

²⁵ This was the basis for the ‘shading’ in Table 5.1, p. 98, of the themes of good governance.

analyses were a preferred method for many years in policy analysis, where quantitative approaches used “scientific” and “technical” models of risk assessment including cost-benefit analyses, life cycle assessment, environmental valuation and others (Stirling, 1998, p. 97-98). These ‘expert-based’ analyses result in quantitative values that give a definitive ‘answer’ to a policy question. A more recent trend has seen the rise of democratic and participatory methods of discourse, where, for example, citizens and non-experts are brought into the process to establish a lay perspective in decision-making. However, these efforts might also be subject to distinctive framings and interpretations of a kind that could serve equally to ‘close down’ decision-making processes as much as they seek to ‘open’ them up (Stirling, 2008).

It seems that both quantitative and qualitative approaches have important contributions to offer to decision-making. Quantitative components allow for traditional appraisal methods to be expressed, while qualitative components allow for an explicit acknowledgement of the possibility of divergent framings that might impact the ultimate ‘decision’. Thus, the methodological design of the elicitation component of this research might usefully take advantage of qualitative sensitivity and quantitatively precise analysis of different governance options in a contested technological area. Such a design would also allow for the recognition that any decision is impacted by both the historical policy and technological circumstances in each country, as well as the unique socio-political context of each individual stakeholder. However before going any further, we must establish some basic criteria against which the particular methodology chosen was deemed preferable to others which operate under similar principles.

4.2.2 Using criteria to inform the methodology selection

As alluded to above, ‘participatory’ decision-making techniques can be critiqued from a variety of angles. Perhaps equally important to evaluating how effective they are in a given context is consideration of how we might select different approaches in the first place. Indeed, some have argued that the methods by which we should select and evaluate ‘democratic’ approaches to participation and appraisal have been under-researched as a whole (Fiorino, 1990; Beierle, 1999; Rowe and Frewer, 2000). For theoretical and empirical reasons, then, it is important to critically understand and validate the selection of a given appraisal methodology.

Since this research is comparing the views of actors across countries in a contentious technology area, a methodology is required that enables accurate and

nuanced elicitation of perspectives on good governance, such that any associated (and/or) systematic patterns may be identified and robustly analysed. Based on this, the following criteria have guided the selection of an appropriate methodology:

- i) it must be able to incorporate multiple views in a symmetrical fashion that does not unduly privilege one type of perspective;*
- ii) it should allow one to distinguish the criteria through which perspectives on 'good governance' are constituted as they relate specifically to possible real-world scenarios;*
- iii) it should elicit a rich body of salient background information concerning the contextual conditions, qualifications and uncertainties related to the applicability and interpretation of these criteria;*
- iv) it should allow expression of normative judgements (within and across perspectives) concerning overall evaluations of particular governance scenarios; and*
- v) it should elicit this information in a fashion that is convenient and accessible to participants, allowing them to validate key aspects of the outcome, rather than leaving this solely to interpretive analysis.*

Considering both the limitations of this research and, more importantly, the criteria above, Multicriteria Mapping (MCM) and Q Methodology are the two methodologies that stand out for consideration.

MCM is a type of multi-criteria decision analysis tool, but is distinct in that its aim is not to identify a single, normatively 'best' course of action, but instead to identify the different underlying reasons, or criteria, that influence people's perceptions of different options (Stirling and Mayer, 2001). It does so by systematically eliciting stakeholder viewpoints on the different options and mapping these diverse perspectives out (DTLR, 2001, p. 128). Q methodology is a type of discourse analysis that was developed in 1935 by the British physicist-psychologist William Stephenson (Stephenson, 1953; Brown, 1996). It shares with MCM the systematic identification of collective views, but in a way that is initially framed by the research investigators and based on responses to textual prompts rather than decision options (Dryzek and Berejikian, 1993; Yearley, 2001). Both methods involve qualitative and quantitative elicitation, but as pointed out by Yearley in his review of MCM, there are distinct advantages to the use of each in different situations (2001). The discussion below will consider how well each of these two methods fulfils the five criteria outlined above. At the end, we expect to establish a more robust, theoretically and empirically grounded justification for the elicitation methodology selected for this thesis.

Criterion i): it must be able to incorporate multiple views in a symmetrical and transparent fashion that does not unduly privilege one particular perspective

MCM was originally conceived to allow stakeholders to assess different policy options for a given issue, with the aim being the construction of a literal “sensitivity map” where the technology and policy choices preferred by individuals, constituencies or agencies at any particular moment, or point of view, could be determined (Stirling, 1997, p. 195). Q methodology was developed with the intention of “providing a way to reveal the subjectivity involved in any situation” from political attitudes to personal judgements (Brown, 1996). Q methodology can reveal patterns in how “elements of different perspectives are related” (Tuler et al., 2005), but in a manner based on the analysis of particular features of discourse, not on the assessment of different governance options. On this criterion, then, Q methodology and MCM equally meet the requirement of systematically, transparently and impartially incorporating multiple points of view.

Criterion ii): it should allow one to distinguish the criteria through which perspectives on ‘good governance’ are constituted as they relate specifically to possible real-world scenarios

Q methodology begins with a set of statements about a particular issue. The statements are pre-selected by the researcher from a wide variety of literatures in order to represent the range of discourses on the topic of research (Swedeen, 2006). They are then presented to the participant for ordering in various ways based on how strongly they agree or disagree with the statement. These ‘Q-sorts’ are statistically analysed to determine what patterns of discourse exist among the participants.

MCM begins with an open-ended set of ‘options’ that vary depending on the context of the research. For example, they might be specific policy options or different ‘scenarios’ of options where a wider range of variables can be brought in. Participants must consider a set of ‘core options’, but can define new options if they wish. The participant is then asked to define criteria that are used to evaluate (quantitatively and qualitatively) each option’s ‘performance’. The criteria represent the individual factors that underlie and influence a participant’s views on the topic at hand. Once the evaluations are completed, a literal ‘map’ of the range of views that can be expressed for a given option when considered against different criteria is produced. In this way, the criteria and their evaluative use provide a window into the perspectives on ‘good governance’ that the research seeks to illuminate. As Q methodology has no such

established way of eliciting similar ‘criteria’ in such a user-defined manner, MCM seems to be a preferable method under this criterion.

Criterion iii): it should elicit a rich body of salient background information concerning the contextual conditions, qualifications and uncertainties related to the applicability and interpretation of these criteria

This type of information is critical for the research as it will enable an explanation of why different interpretations of good governance exist. Through the MCM interview, a vast array of verbal information is collected from the individual as he works through the different criteria definition and option scoring stages. In addition, the analysis package for MCM allows multiple criteria, scores and other sources of information to be tested and analysed in different ways. Thus, MCM allows the full context of the evaluations of governance options, in terms of how the criteria are developed and defined, to be revealed and explored. Q methodology has no similar mechanism for drawing out a similar level of background information. Once the participant has sorted the statements, the final analysis is done at a statistical level and overall conclusions about the way each stakeholder’s views relate to the overarching factors are made. Thus, the inability of Q methodology to elicit background information and detail is a critical shortcoming in light of the requirements of my research.

Criterion iv): it should allow expression of normative judgements (within and across perspectives) concerning overall evaluations of particular governance scenarios

Yearley’s review of MCM concluded that though MCM was not explicitly developed for the purpose of delivering prescriptive policy recommendations, it can easily be utilised to do so (Yearley, 2001). More importantly, MCM can deliver the “reasons for differing views” as well as the “practical implications for the overall performance” of different governance options for the technology being considered (emphasis in original, Millstone et al., 2006, p 60). Similarly, it can aid in the identification of points of disagreement or synergy that may not otherwise be readily apparent between the criteria. Though Q method can be interpreted to deliver normative judgements, these are not identifiable in a way that can be interpreted according to the different criteria. That is, the results of a Q sort can only be interpreted in the context of the responses to all the Q statements. MCM, on the other hand, is able to accommodate different perspectives on the options as they may vary according to individual criteria. Thus, normative judgements can be gathered both at the level of overall governance of an institutional configuration, and at the distinct level of the criterion.

Criterion v): it should elicit this information in a fashion that is convenient and accessible to participants, allowing them to validate key aspects of the outcome, rather than leaving this solely to interpretive analysis.

Q methodology leaves much interpretation to the analyst. From the initial stages of the research and the identification of the Q statements to the ongoing analysis of the empirical data after the interview is conducted, there is a certain degree of interpretive flexibility afforded to the researcher. This is particularly the case in the final stages of the analysis, the aspect that is most crucial for this fifth, and final, criterion. After a Q sort is completed, it is the analyst who conducts the validation, assessment and final interpretation of the research results in order to determine which views, framings and assumptions are revealed and the implications for the wider research question.

With an MCM analysis, the participant is able to validate the performance rankings of each assessment made, both under individual criterion and at the aggregate level under all criteria. This step is particularly crucial at this latter point in the interview when the final performance ranking ‘map’ for all the options is considered. If there are any aspects of this map that do not seem ‘right’ to the participant, he is able to explore why this is the case and make changes to any part of the evaluation, if necessary. The intention is that by the end of the interview, the participant must be satisfied that the final performance ranking is consistent with his ‘worldview’ in relation to the options. If any changes are made, the analyst is aware of any points that may or may not have originally reflected the views of the participant and why. This information serves as a rich source of information and data in the analysis.

In conclusion, based on the analyses above, it is clear MCM provides a more appropriate elicitation methodology for the particular aims and objectives of this research. It can transparently incorporate multiple views, identify synergies between competing options, elicit criteria for governance configurations, assign weights to value preferences, and lend itself to normative judgements about the constitution of ‘good governance’ for hESC research. The remainder of this chapter will focus on a detailed discussion of the MCM methodology, including the interview process and data analysis.

4.3 *Multicriteria Mapping in Detail*

4.3.1 Overview

Multicriteria Mapping (MCM) is a software-assisted, multi-criteria decision analysis-based technique used to assess different ‘options’, or ways forward, for contested areas of science and technology policy. This assessment is done through analysing the respective strengths and weaknesses of different options under participant-defined, evaluative ‘criteria’. It is distinct from other decision analysis techniques of this type in that its aim is not to identify a ‘best’ decision, but instead to identify the different underlying reasons, or criteria, that influence people’s perceptions of different options (Stirling, 1997, 1998; Stirling and Mayer, 2001).

The MCM process is based in a recognition of the limitations of more complex multi-criteria, cost-benefit, or other risk analysis approaches which try, and fail by the conditions of Arrow’s impossibility theorem (Arrow, 1970, as explained in Stirling 1998), to identify singularly, normatively ‘best’ decisions on the basis of a complex series of calculations and considerations. Rather, MCM aims to enrich our understanding of how and why different decision options may appear favourable under some conditions and less so under others. Thus, it allows exploration of divergent framings and interpretations through a transparent, reflexive and iterative appraisal process. The result is an array of open qualitative, and structured quantitative, information which yields a rich picture of the conditionalities and framings associated with each perspective. This information takes the form of literal ‘sensitivity maps’ that can be evaluated to expose key features and perceptions of governance frameworks that are favoured under particular socio-political viewpoints (Stirling, 1997).

In its entirety, the MCM process can be broken down into six distinct phases: 1) designation of technology area, 2) research into scientific and policy literature, 3) identification of participants, 4) definition of options, 5) individual interviews, and 6) analysis. The first two of these steps are covered in the general case study approach and the policy literature review discussed above. The remaining phases are specific to the MCM process. Much of this is covered in the sections below, however, for purposes of space and clarity, some of the more detailed methodological discussions are provided in relevant Annexes.

4.3.2 Identifying interview participants

An MCM process aims to capture the ‘envelope’ of expert and stakeholder views and relevant dimensions of a policy debate. In other words, one must include views in the ‘centre’ of the debate, as well as those on the periphery. Based upon the initial review of the policy, scientific and historical literature discussed above and presented in Chapter 2, several stakeholder perspectives were initially defined as important to ‘capture’ within the envelope. These include:

1. *Patient advocacy groups*
2. *Scientific advocacy groups*
3. *Religious advocacy groups*
4. *Opposition policy advocacy groups*
5. *Scientists*
6. *Professional body representative groups*
7. *Industry Executives*
8. *Policy-makers and Regulators*
9. *Bioethicists*

Each group has an important role to play within the socio-political governance context in which decisions about hESC research are made. All four types of advocacy groups are relevant because they represent key points of view in the debate and each has an interest in particular governance strategies for hESC research. Scientists are the ones conducting the research and so have first-hand, technical experience in the challenges science can pose to governance and policy-making. Industry executives, like professional body representative groups, have a market or related professional interest and so can be said to hold a unique set of views on aspects of governance most relevant to them. Policy-makers and regulators are ultimately responsible to the public for the governance decisions that are made and related ramifications. Finally, bioethicists are a relatively newer entrant to policy advisory circles but are important in this field. Their deliberations are said to provide a forum for more nuanced social, cultural and ethical governance considerations.

As it is important to capture both a range of depth of views, at least two or three people will be interviewed per group, with some adjustments made depending on resource constraints and national context. For example, in the US, it was important to

explore whether regional differences existed between individual states. A full table of the final numbers of interviewees per group is provided in Chapter 7 (Table 7.1).²⁶

Interview participants were identified through a range of methods, but all were initially contacted in a standardised manner through email or phone call.²⁷ Initial contact with potential interview participants in the US was first made by reconnecting with interview participants who had participated in a previous study of the authors' using MCM in relation to hESC policy options in the US (Morgan, 2004). In an email, these participants were reminded of this earlier research and the new research topic was introduced. Of these eleven participants, seven agreed to participate in this doctoral research. The remaining individuals either referred us to someone new or were not reachable as they had moved positions. Contact with new individuals was made through 'cold' emails or phone calls. Of these 'cold' contacts, a positive response rate of over 50% was achieved, with either the individual agreeing to be interviewed or referring me to a colleague. Participants were also identified through references given at the end of MCM interviews.²⁸ This 'snowballing' effect was a rich source of new interviewees. However, participants were identified equally through 'cold' contacts and 'snowballing'. This allows me to remain reasonably confident that there is not too much overlap in my dataset in terms of shared perspectives.²⁹

4.3.2 Defining the Options

An MCM interview begins with an open set of options. These options provide alternative 'ways forward' for the problem being evaluated and can be of many types, for example specific policy options (Stirling and Mayer, 2001; Millstone et al., 2006; McDowall and Eames, 2007), or diverse pathways (Leach et al., forthcoming; Thompson et al., 2010). Regardless of the type, it is important that each option is sufficiently distinct from the others in that it addresses different aspects of the issue, in this case, the governance of hESC research.

Options feature in an MCM interview in three distinct ways as *core*, *discretionary* and *additional* options. The core options are pre-defined by the

²⁶ The table of interviewee codes in Annex E also provides this information.

²⁷ With the caveats given below about 'cold' emails versus those the authors had prior contact with, all emails were of a standard format and content. A sample of both types of emails are provided in Annex D.

²⁸ At the end of an MCM interview, a participant was often asked to recommend colleagues who might be interested in participating.

²⁹ One might expect that mutually referred colleagues might share similar perspectives on good governance, especially if they are part of the same actor network.

interviewer and evaluated by all participants. Because they are evaluated by everyone, it is the core options that enable systematic and structured comparison across all interviewees. Thus, great care is taken to ensure these options are sufficiently representative of the key features of governance.³⁰ Discretionary options are also pre-defined by the interviewer, but participants have the option of choosing whether to evaluate some, all or none of these options. In the case of this thesis, discretionary options are used to ‘round out’ the scope of the options. Finally, if the participant feels that none of the pre-defined options capture an aspect of governance he believes is important to discuss, he is able to define his own ‘additional’ options. These can take any form or structure, but are usually modelled on an existing option so that they can be evaluated in a consistent manner.

The MCM options for this thesis are structured according to the ‘dimensions of governance’ presented at the end of the previous chapter. These dimensions revolve around the questions: 1) Is the principal governance mode centralised or devolved? 2) Do mechanisms for regulatory oversight provide detailed prescriptions or general guidance? 3) Are associated deliberative processes ‘democratic’ (participatory) or ‘technocratic’ (expert-based)? The option definition process addresses these dimensions by proceeding in an iterative fashion through two independently conducted stages. A description of these stages is provided in Annex B, but a brief summary is given here.

The first stage involved developing eight ‘abstract’ options based on the potential combinations of the three central dimensions. The second stage was to review national governance frameworks and develop country-specific options. Once two sets of options had been prepared, a ‘matching process’ commenced through which a core set of options were identified that were based upon the abstract dimensions, but grounded in ‘real-world’ examples. We decided to base the governance options on country-specific examples so as to simplify the ‘conceptualisation’ of the options by the participant. Due to the fact all participants were specialists in their field, it was reasonable to assume they would have at least a working level of knowledge about different country’s governance approaches. Eventually, six core options and three discretionary options were arrived at, covering seven countries. The full description of the options that were used in the MCM interviews and an accompanying summary table are given in Annex C, but their titles and short summaries are listed below. The countries indicated in parentheses next to the titles are those the option was based upon.

³⁰ The process by which the core options were identified for this thesis is discussed later in this section.

Core Options

1. Detailed Centralised Oversight (UK): Centralised governance with detailed regulations implemented by an expert statutory body that is empowered by legislature and is informed by occasional public involvement initiatives.
2. Expert-led Framework (Sweden): Devolved ethical, expert-based oversight subject to central general laws.
3. Detailed Expert Oversight (Germany): Centralised, expert governance through detailed regulations established by legislature and carried out by central scientific institution.
4. Devolved Authority (Australia): Devolved legislative authority subject to central detailed regulations and expert review with occasional public participation.
5. Mixed Central/Devolved (US): Centralised expert governance with detailed regulation of federal public research funds, and a variety of devolved governance frameworks.
6. Ethics-led Governance (Israel): Centralised, expert governance through general laws with ethical oversight.

Discretionary Options

7. Devolved Democratic Governance: Devolved democratic governance through general laws.
8. Centralised Democratic Governance: Centralised democratic governance through general laws.
9. Centralised Regulatory Authority (Canada): Centralised detailed regulation by expert statutory body subject to oversight by legislature.

Three additional options³¹ were defined by participants over the course of the 57 interviews and no discretionary options were evaluated.³² When asked, all participants indicated a satisfaction with the coverage of the six core options and thought they comprehensively covered relevant dimensions of governance.

³¹ The definition of these options as defined by the participants can be found in the summary overview of MCM findings given in Annex F.

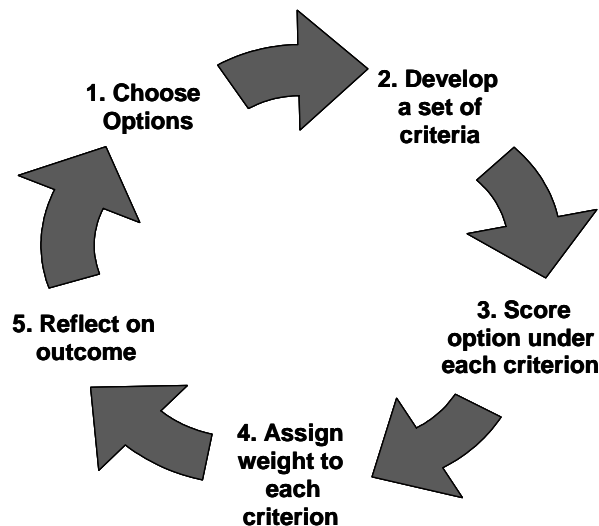
³² An important methodological point should be made here. The MCM interview process began with only the first five of the six core options listed above. After an initial set of interviews had been conducted, the sixth core option, which was previously a discretionary option, was added. Some individuals had already chosen to evaluate it as a 'discretionary option' and had commented that the option filled an additional 'dimensional space': that of (largely) self-governance. As it was added 'late', so to speak, 12 individuals in the US and eight individuals in the UK did not evaluate the sixth core option. It was felt that returning to these individuals and conducting a single option assessment at a later stage would potentially bias the results as the participant might not be in the same frame of mind for the later assessment. During the analysis, great care was taken when making any judgements about the sixth core option given fewer participants evaluated it than others. No claims were made about the significance of any findings from this option where insufficient numbers of participants had evaluated it relative to the whole.

4.4 The MCM Interview Process

4.4.1 Introducing the MCM Interview

An MCM interview is an open, reflexive, transparent and relatively simple process (in theory) which takes the participant through what is essentially a decision analysis process, from selecting options for consideration to evaluation of those options under different, evaluative criteria. The stages of an MCM interview are summarised in Figure 4.1 below. An MCM interview is mediated through the use of a computer software programme, which allows one to record the qualitative and quantitative information in real-time. This feature also allows the participant to validate their evaluations throughout the interview. The discussion of the MCM process below will be aided by the inclusion of screen shots from the software programme, *MC Mapper*.³³

Figure 4.1: Stages of an MCM Interview



Each stage is discussed in more detail below, but can be summarised as follows:

- 1) *Choose options: the set of options the participant is asked to consider during the interview are discussed, and any discretionary or additional options are identified,*
- 2) *Develop a set of criteria: he is then asked to define evaluative criteria that will be used to evaluate each option's performance,*
- 3) *Score options under each criterion: he evaluates the options under each criterion,*

³³ MC Mapper is an open-source software programme developed by Professor Andrew Stirling and colleagues at the University of Sussex. Details about the software algorithms can be found in Annex G.

4) Assign weight to each criterion: he assigns relative weightings to the criteria, and

5) Reflect on final outcome: the final 'map' of performance rankings, as well as the whole process, is reflected on.

It is important to note that though these stages are presented in a sequential order, and the interviewer must follow a specific protocol in going through them, the participant is free to return to earlier stages of the interview at any time. For example, the participant may add new evaluative criteria, select a discretionary option for evaluation or change an assessment score at any point. This is one example of how MCM provides an open and reflexive evaluation process whereby they are able to continuously reflect back upon previous assessments in light of new insights throughout the process.

Before the formal interview stages commence, a description of the research project is given and the participant is introduced to the MCM process.³⁴ Participants are also explicitly made aware of the scope of the research. This is essentially two-fold: 1) the governance options are restricted to hESC research and do not, therefore, extend to clinical applications and associated governance considerations;³⁵ and 2) the use of the term 'governance' in this research context (see definition in background document and in the previous chapter). Finally, participants are assured that the views they express in the interview will be presented as their own and not as officially representative of their respective organisations.³⁶ However, in the MCM analysis, the organisational affiliations of each individual are taken to indicate a particular shared point of view, or perspective, of the participant as a result of these affiliations. Thus, though individual organisations are not officially represented, the professional fields the individual is a part of are taken to be indicative of a given perspective they hold.

4.4.2 Choosing the options

This stage of the interview is relatively straightforward. The options are discussed with the participant, who is encouraged to ask questions or seek points of

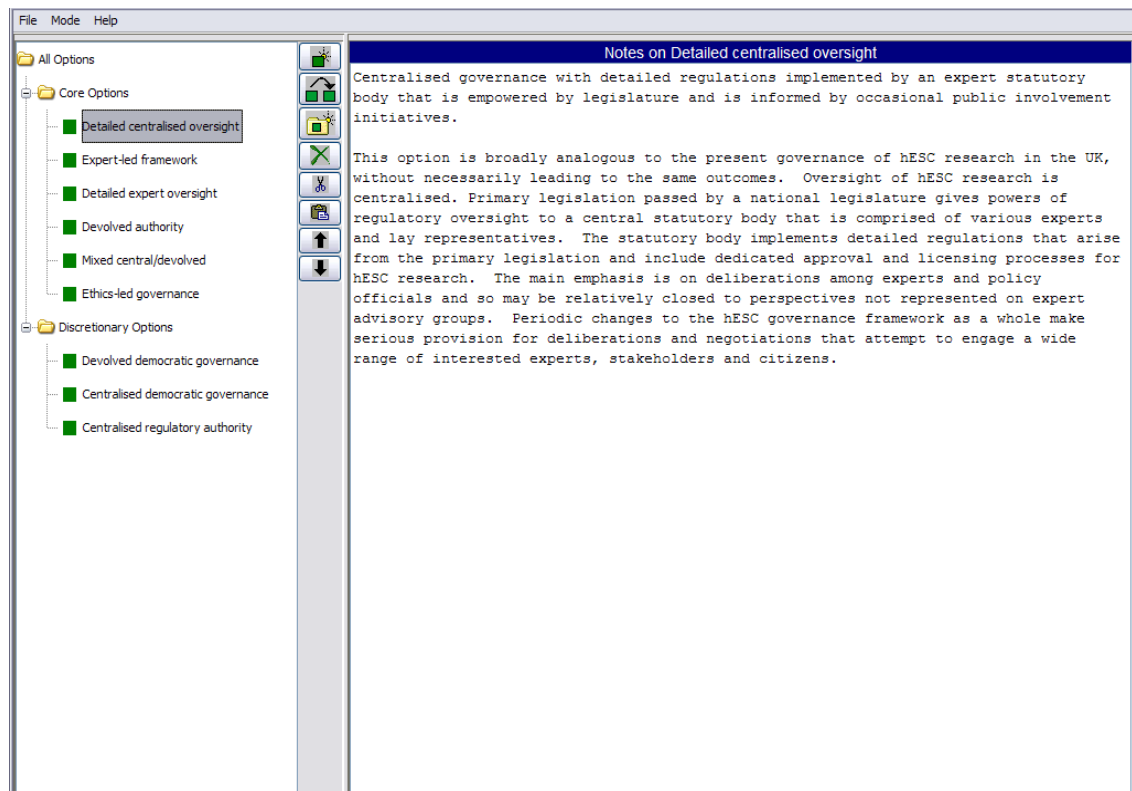
³⁴ Though participants are given two briefing documents prior to the interview, most participants generally have not read through these in their entirety. The two briefing documents and a sample covering letter/email are provided in Annex D.

³⁵ For example, were the scope of the research to extend to clinical applications, clinical trials and other regulatory procedures would need to be included within the governance options. As mentioned earlier in this chapter and at earlier points in the thesis, this research was specifically bounded as looking at good governance in the context of hESC *research* and not the clinical aspects, per se, although these necessarily factor in to governance discussions as the future clinical and therapeutic promise of hESC research is a key factor in this wider socio-political context.

³⁶ Though the majority of participants did not request anonymity, for purposes of confidentiality all responses and participant identities have been made anonymous for this thesis.

clarification at any time. During this stage participants are also asked if they would like to consider any of the discretionary options or define any additional options. Generally, participants had not read through the options in great detail prior to this time, but, in about 25% of the interviews, the participant had read through the options and made notes or comments in the margins of their introduction pack. Some had gone so far as to generate an initial list of criteria. Though helpful in the sense that the participant had a good grasp of the interview methodology, this did not always mean the interview more accurately or authentically reflected their personal view. Each participant proceeded through the interview at their own pace and regardless of their preparation beforehand, their unique set of views, framings and judgements still emerged.

Figure 4.2: Screenshot of Option Definition Stage of MCM Interview



The figure above shows a screenshot of the MC Mapper software at the option definition stage. All the option titles are listed on the left hand side, while their definitions are displayed on the right-hand side of the screen.

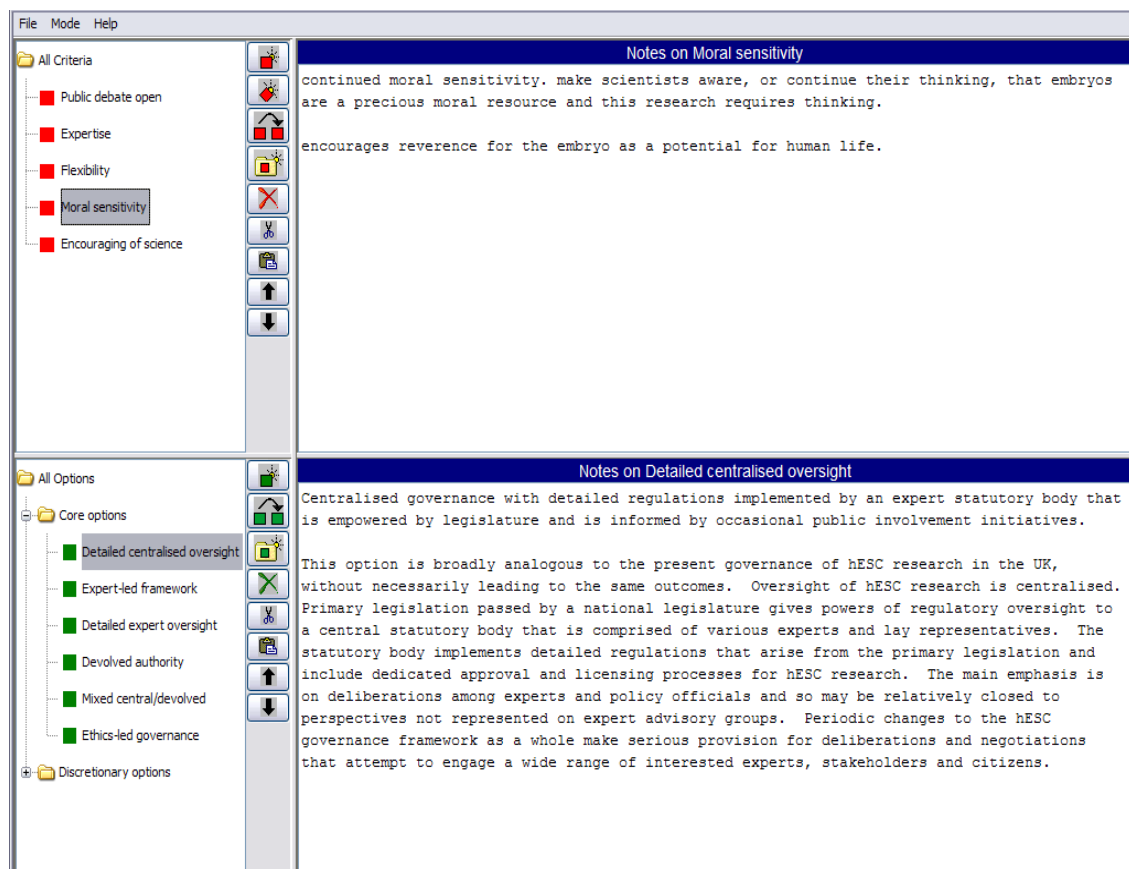
4.4.3 Defining criteria

The second stage of an MCM interview is the definition of the evaluative criteria. Criteria are the different judgements, assumptions, technical views, personal

beliefs, and so on that a participant uses to evaluate the options. Participants can define as many or as few criteria as they like.³⁷ They are also able to define ‘criterion of principle’, meaning a criterion that reflect views on which there are moral absolutes or ethical thresholds against which no trade-offs can be made. Definition of a criterion of principle means the participant is able to rule out one or more of the options on the basis that it violates such ‘absolutes’.

The figure below shows a screenshot from the MC Mapper software at the criteria definition stage. As participants define their criteria, a new criterion in the upper left-hand corner box is created and notes are taken on the way the participant defines it in the larger box on the right-hand side of the screen under the ‘Notes’ panel.³⁸

Figure 4.3: Screenshot from Criteria Definition Stage of MCM Interview



To date, most MCM projects have been primarily concerned with the final analysis of policy options and the views and framings that influence the relative option performances (see Stirling and Mayer, 2001; Davies et al., 2003; Millstone et al., 2006;

³⁷ Full details about the number of criteria defined in all MCM interviews, including any ‘criterion of principle’, can be found in the summary data of MCM usage in Annex F.

³⁸ Though not shown here, a screenshot of the MC Mapper software when a criterion of principle is defined can be found in Annex F.

McDowall and Eames, 2007). However, this research is concerned with notions of good governance. Therefore, the criteria are of primary importance, not only in how they are defined, but also in how they are used to evaluate the options in terms of scores given, uncertainties expressed and associated nuances illuminated.

Due to the central importance of the criteria themselves, it is of utmost importance that all participants share a common understanding of what a criterion is. Past experiences with MCM have revealed that participants can struggle in the criteria definition stage (see Morgan, 2004). They may not understand what a criterion is or what the criterion will be used for and often ask for examples to aid their thinking. Methodologically, such examples are difficult to give. Examples given to one participant would need to be given to all without running the risk of unduly biasing the results. Though participants are provided with a worked example of an MCM exercise, including criteria examples, of an entirely different scenario (the case of energy provision),³⁹ this is not always helpful. In considering the central topic of this research, whether distinct perspectives on good governance are discernible, and the hypotheses that follow, in discerning these perspectives one can probe the diversity of framings, conditionalities and viewpoints that affect how the perspectives are constructed, the importance of eliciting *meaningful* criteria in a *consistent* way becomes paramount.

In order to address this, a ‘thought bubbles’ handout was developed and given to all participants (see Annex D). Of course the danger in using a ‘prompt’ sheet like this is that it risks increasing the criticism of interview bias that it is meant to address. In order to mitigate this, several steps were taken. First, only single words are given in the ‘thought bubbles’. Thus, participants have to elaborate on them in a meaningful way in order to use them as criteria. To further emphasise this, the instructions at the top of the handout clearly state the bubbles “are only prompts” and if the participant would like to use them, they should “define them in a way that is meaningful” to them. Thus, if the handout is used, the participant is only drawing on single words and each interpretation is unique to an individual.

Second, not only do the written instructions indicate the bubbles are only meant to be a guide, but the verbal and physical interaction with the participant attempts to minimise reliance on the bubbles. When the criteria definition stage in an interview is reached, the definition of criteria is reviewed and the handout is briefly shown to the participant. It is explained that it is a list of ‘ideas’ or ‘thoughts’ that might help them to

³⁹ See the example given in the background information documents included in Annex D, p. 306.

think about criteria. After being given enough time to read the instructions at the top and glance through the bubbles, the participant is asked if any criteria occurred to them while preparing for the interview or while discussing the options. As this is said, the thought bubbles handout is discreetly, but purposefully, moved to the side and out of the participant's line of sight. The aim is to verbally and physically distract the participant from using the prompt sheet before developing his own ideas.

Third, and finally, approximately 45 'thoughts' bubbles are included in the handout. This is about the same number of discourse statements that are used in a Q-sort and so might in this broad sense be considered methodologically valid in terms of the requisite levels of refinement of the literature required in order to avoid bias. Moreover, each issue listed on the prompt is 'grounded' in wider policy literature specific to hESC research, theoretical literature in a variety of academic disciplines specific either to hESC research or biotechnologies, and wider governance and STS literatures. The aim was to ensure, as comprehensively as possible, that the majority of the issues discussed in the wider literature and policy discourse, were covered within the bubbles.

The results from the interviews suggest that this approach was successful in minimising bias and producing meaningful criteria. Less than half of the participants interviewed for this research actively used the prompt sheet, but the use of the sheet varied. Some used it only for defining the first few criteria, but once they became comfortable with the idea of criteria they would put it to the side. Others started with their own criteria, but would look to the sheet after an initial brainstorm as if to seek out additional ideas. Even when different participants based criteria on the same thought bubbles, the definitions of the criteria were unique and, in some cases, completely divergent in their meaning. Thus, we can be reasonably confident that the prompt sheet did not bias the criteria definition in any significant way.⁴⁰

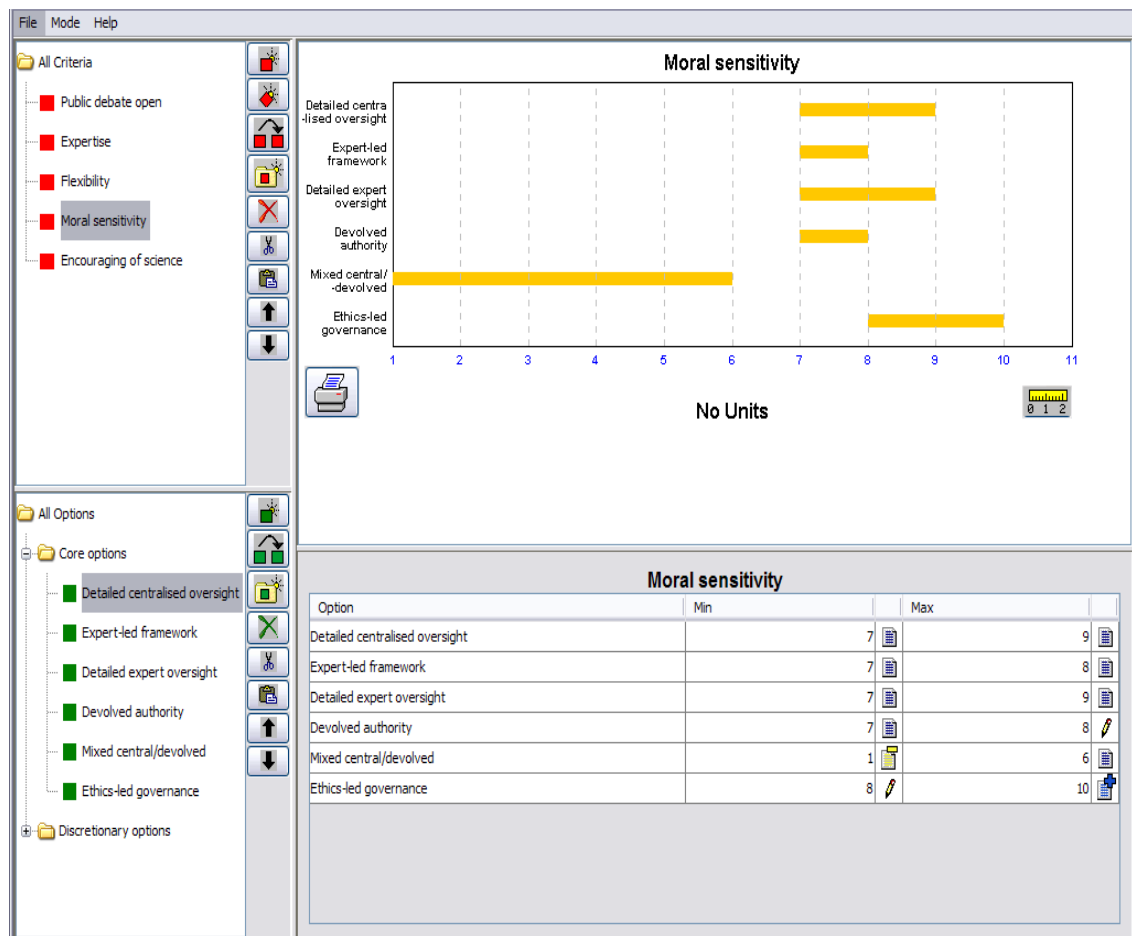
4.4.4 Evaluating the options

This stage is, by far, the most complex and time consuming part of the MCM interview. Participants are asked to evaluate each of the options based on how well it 'performs' under individual criterion. To do the evaluation, participants are asked to give a pessimistic and optimistic score to each option on a scale of the participants choosing (usually 1 to 10, or 1 to 100). These scores are recorded in a table as shown in

⁴⁰ Further detail of the relationship between 'freely-defined' criteria and those in the prompt sheet is provided in the summary of MCM interview findings in Annex F.

the screenshot below, with ‘minimum’, or pessimistic, scores recorded on the left and ‘maximum’, or optimistic scores, recorded on the right. Notes are taken in each of the ‘pencil’ boxes (which pull up a dialogue box when clicked on) about the participant’s reasons for assigning particular scores. These reasons might include the assumptions being made about optimistic or pessimistic conditions, the conditions themselves, or the relationships between evaluation assessments. The bar rankings seen in the top half of the screen come up automatically, so the participant is able to see the relationship between options at all times.

Figure 4.4: Screenshot of Scoring/Assessment Stage of an MCM Interview



As pointed out earlier, we are most interested in the way participants use the criteria to evaluate the options (as expressions of good governance), as opposed to what they think of the options themselves. In this regard, it is important to note two distinct ways the participants evaluated the options. Some were comfortable evaluating the options in the ‘abstract’, that is they understood the options were only based on different country models for illustrative purposes and they rely on these abstract dimensions to

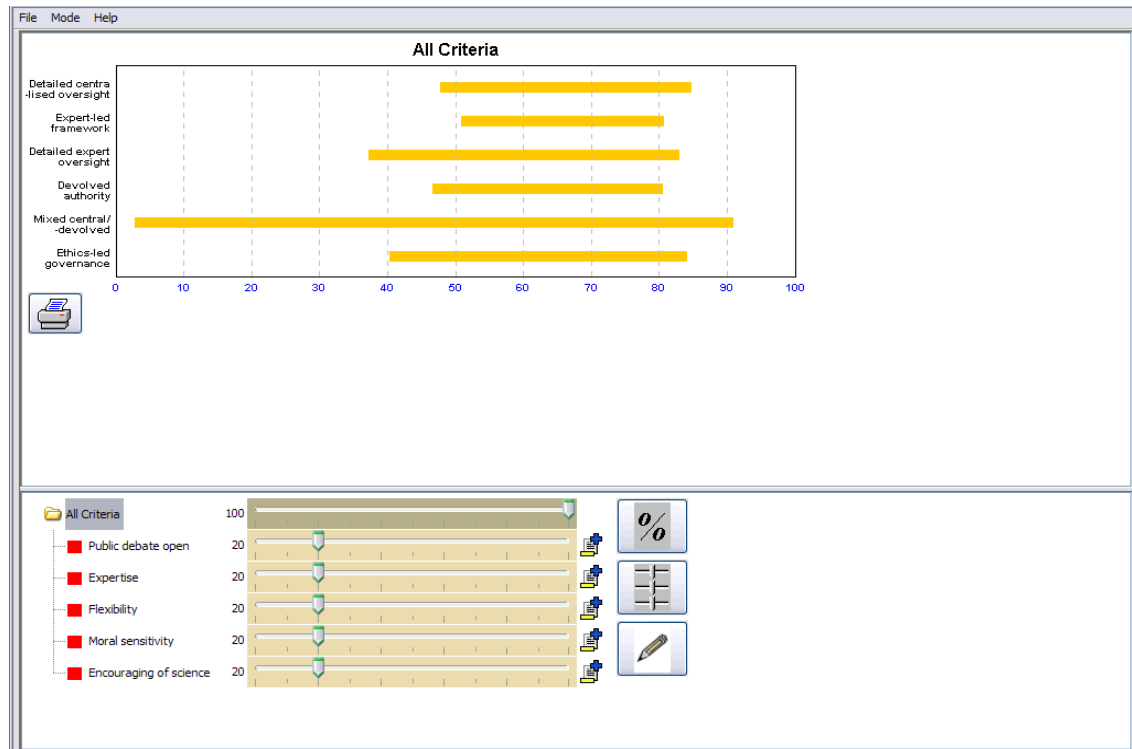
conduct the evaluations. The second pattern is where participants based their evaluation more on their knowledge of the country the governance option is related to.

With regards to the research question, these differences do not significantly affect the findings. As has been repeatedly stated, the interest of this research is to understand perspectives on good governance. We expect these perspectives to be culturally, politically and individually contingent in ways that will emerge through the definition and weighting of the criteria and the respective option assessments. Thus, as long as the qualitative information about the criteria and the assessments are elicited, variations in the interpretation of the options should have little impact on the overall research question as it relates to understanding *how* perspectives on good governance are *constituted*. Nevertheless, the point about interpretation is methodologically important, and one that was considered throughout the analysis.

4.4.5 Weighting

The final stage of an MCM interview is the weighting of criteria. Here participants can express the relative importance of each of the criteria they have defined. They are encouraged not to think about the ‘rank order’ of the criteria, but the *relative* importance of the criteria in terms of the assessments of options themselves. In other words, it is not just which criteria are more important, but the ‘amounts’ (in relation to minimum and maximum option scores) by which each criterion might be traded off against others.⁴¹ In the software, weighting is done using a sliding scale of 0-100 (pictured below). The weights are normalised and the final performance rankings of the options under all the criteria can be seen. The figure below shows a screen shot of the weighting bars and final performance rankings.

⁴¹ Recall that criteria that are identified as not being susceptible to trade-offs are addressed in the MCM methodology using ‘principles’.

Figure 4.5: Screenshot of Weighting Stage of an MCM Interview⁴²

Importantly, as the participant adjusts the weightings, he sees the aggregate performance of the options under all the criteria he has defined. That is, the final performance ‘map’ of the different options as expressed through the length and relative position of the bar charts moves in real-time as the participant adjusts the weightings. This allows the participant to understand how the weightings affect option performance and aids in the crucial ‘validation’ step that was discussed in Section 4.2.2. For example, if the participant’s initial rankings are found to be inconsistent with their views, then we can discuss why this might be the case. If the participant is simply surprised, reflections are made on why he is surprised and how the final rankings differ from any expectations. However, if the participant is unhappy because the final rankings are incompatible with an organisational or personal view, we might again explore these reasons and, if necessary, adjust scores or weightings.⁴³ Such transparency in understanding the framings and socio-political views affecting the final performance map is not something easily found in other methodologies and provides a rich source of material for the later analysis, as well as an important validation step in the method.

⁴² The reader may note that in the above example all the weightings are equal. This reflected the view of the interviewee that all criteria were equally important, however this was not usually the case with most interviewees.

⁴³ In such instances, both versions of the MCM weightings and options scores are saved so that they can be referred to by the interviewer in later stages of analysis.

4.4.6 Discussion of performance rankings

Finally, at the end of the interview the final ‘map’ of the performance rankings of the options is discussed with the participant. Most participants find the map accurately reflects their views they initially had about the different options, but there is often surprise at the extent of the uncertainty ranges or the relative performance rankings. In this study, no participant asked to change any scores at this stage, but some did want to return to earlier scores to understand which assessments were affecting the final performance rankings and in what ways.

We have now completed our description of the MCM interview process. The next section will discuss how all of the MCM interview data was analysed.

4.5 Analysis of MCM Interview Data

4.5.1 Introduction to the MCM Analysis package

In total, 57 MCM interviews were conducted where a full set of MCM data was collected.⁴⁴ Three interviews were conducted in which the participants declined to participate in the full MCM interview. In one instance this was due to unexpected time constraints on the interview with no opportunity to reschedule. In the other two instances it was because the participants felt uncomfortable with a certain aspect of the interview process. In one case the participant was opposed to hESC research on religious grounds and so he was not willing to discuss the governance of such research at all. Though the participant was given the option of defining a criterion of principle to address this, he declined. In the other case, the participant did not feel comfortable making judgements on governance options in the abstract or even when considered in their nationally-based context. In all three cases, semi-structured interviews were conducted. In two of them, the participants defined the types of criteria that were important to them in thinking about governance issues for stem cell research (including non-embryonic stem cell research).⁴⁵

⁴⁴ In two of these 57 interviews, the participants worked together for a US state policy department. They conducted the MCM process sitting together. Upon sitting down to conduct the interview they found they had each defined similar criteria, and so they each used the same criteria names, with slightly different definitions. For some options different scores were given and each individual gave different weightings. This detail is given here because in some of the supporting Annex material it may appear to the reader that one interview was counted twice, however this was not the case.

⁴⁵ As they did not complete a full MCM appraisal, these criteria were not included in much of the analysis of interview-generated empirical data. However, they are included in the table of criteria in Annex H.

In order to ensure completeness of the database before beginning the analysis, all interviews were recorded and listened to after the fact in order to ensure all information from the interview was accurately recorded in the interview database.⁴⁶

The 57 MCM interviews resulted in a dataset composed of 310 individually defined (and fully evaluated⁴⁷) criteria and 1,815 individual option assessments. This is obviously a vast amount of information, all of which must be qualitatively and quantitatively analysed for content, themes and insights. Generally speaking, the analytical strategy (Yin, 2003) of an MCM analysis is one that is driven by a process termed ‘hypothesis-testing’. Through a process of systematically generating testable hypotheses and applying them to the data, one is able to develop a sophisticated and structured understanding of the large amounts of quantitative and qualitative data generated. This process of ‘hypothesis-testing’ requires several analytical steps and proceeds through a process summarised in Table 4.1 below.

Generally speaking, the analysis process can be summarised as first grouping the data into meaningful, ‘analysable’ units, or categories, and then generating quantitative and qualitative representations of the data according to those categories. Quantitative data are shown as performance ranking charts of the governance options according to the particular categories defined, and qualitative data are criteria definitions and associated option evaluations and weightings. By looking for systematic patterns in the quantitative option performance rankings and qualitative characteristics of different categories, a type of ‘heuristic-based’ analysis is used as a starting point. One can then dig deeper into both the quantitative and qualitative data underpinning areas of analytical interest to understand why and how particular patterns emerge.

⁴⁶ This was done either through transcribing parts of the interview into a Word document and then pasting relevant notes, ‘nuggets’ or additional information which was not captured in the interview into the database, or simply directly inputting material into the database while listening to the recorded interview. While the former method was the initial process the author followed, she was afflicted with a serious case of Repetitive Strain Injury halfway through the analysis for which medical attention was needed. At this point it was recommended that the stage of transcribing into a Word document was skipped and the updates made directly into the database. This was approved by both supervisors as the outcome of either path was deemed to be the same – that is, updating of the database with all relevant interview material.

⁴⁷ A total of six criteria were defined in six different interviews that were not fully evaluated under all the options. However, these criteria were assigned weights. The implications of this for the analysis of the rankings are negligible, however in a few instances there are small implications for the analysis of the weightings. Where this is the case, this is noted in the text in the following pages.

Table 4.1: Analysis of Stakeholder Interviews⁴⁸

MCM Interview Stage	MCM Analyst Stage ⁴⁹	Analysis of Stakeholder Interview Data ⁵⁰
Identification of stakeholders	Grouping of stakeholders into meaningful ' <i>perspectives</i> '	Qualitative analysis of interviewee's background and any other pertinent information that may provide insights into their framings and views
Governance option definition	Grouping of options with similar features into ' <i>clusters</i> '	Qualitative textual analysis of discussions around the policy options
		Qualitative textual analysis of additional options defined by participants
Identifying and weighting criteria	Grouping of criteria addressing similar themes into ' <i>issues</i> '	Qualitative textual analysis of criteria definitions and discussion around criteria definition
	Quantitative analysis of issues by numbers of criteria, numbers of participants defining criteria within the issue and relative distribution of issues among perspectives.	
	Generation of ' <i>weighting extrema</i> ' charts under different issues for different perspectives	Qualitative textual analysis of criteria weighting amongst individuals and across ' <i>perspectives</i> '
Assessing option performance	Generation of ' <i>performance ranking charts</i> ' for: all criteria for each individual; all criteria under various perspectives; individual issues under various perspectives.	Qualitative textual analysis of the option assessments under individual criteria by individual stakeholder and at the level of issues by perspective
	Generation of ' <i>uncertainty</i> ' and ' <i>ambiguity</i> ' charts for various combinations of issues and perspectives.	Quantitative analysis of the option assessments across and within perspectives, including analysis of pessimistic and optimistic scores by both ' <i>rank means</i> ' and ' <i>rank extrema</i> '
	Generation of textual reports based upon different configurations of perspectives and issues.	Qualitative textual analysis of the conditions and assumptions specified under pessimistic and optimistic conditions
		Quantitative analysis of the option assessments under various issues across and within different perspectives
		Evaluation and incorporation of methodological scoring differences across and within stakeholder groups.
Review of final option rankings	Generation of performance ranking charts as above.	Qualitative textual analysis of thoughts on final performance scores.
		Qualitative assessment of procedural and methodological issues and implications.

⁴⁸ This table builds on those in (Morgan, 2004) and (Davies, et al, 2007) as well as guidance found in the Multicriteria Mapping Analyst Handbook, accessed at www.multicriteriamapping.org.

⁴⁹ All terms indicated in '*italics*' will be described in more detail in the sections below.

⁵⁰ All qualitative textual analysis is based on information entered in the MC Mapper software and subsequently uploaded into the MCM Analyst database as well as additional information compiled through the review of the interview recordings.

In order to begin organising the MCM data into more manageable units of analysis, the *MCM Analyst* package was employed.⁵¹ This software first facilitates the transfer of all the quantitative and qualitative information from the interview into a Microsoft Access database. The database is structured so that the interview data can be displayed in various forms, tables and queries. This structure enables one to group the interview data in a dynamic and iterative way so that multiple hypotheses can be tested. Examples of groupings are described below and further elaborated on in the empirical findings presented in the next two chapters. The database is also linked to a set of Microsoft Excel spreadsheets. This facilitates the generation of performance rankings and other analytical charts for heuristic analysis. Finally, the *MCM Analyst* software also allows for generation of textual reports that contain relevant qualitative information pertinent to a particular configuration of the data one is testing. Thus, the combination of quantitative data in the spreadsheets and qualitative data in the textual reports allows for side-by-side comparison of the heuristic indicators and the detailed textual data. The sections below provide additional information about how each of these stages proceeded for this thesis study.

4.5.2 Groupings of data: clusters, perspectives and issues

As pointed out above, the hypothesis-led analysis of MCM data is done through identifying patterns or points of comparison in the option performance rankings. However, in order to analyse the data in a meaningful way, the data need to be grouped and ordered according to the hypothesis being tested. There are many ways to ‘cut’ the empirical data and the different types of ‘cuts’ are dependent upon the hypothesis. These cuts of the data into analysable categories take the form of *clusters* of options, *perspectives* of individual participants and *issues* emerging from related criteria.

Clusters are groupings of options that share similar features. While full use of clusters as a unit of analysis was not useful for this thesis due to the small numbers of options, they are a useful analytical unit when the number of policy options exceeds a manageable number (see, for example, Millstone, 2006).

Perspectives are a grouping of viewpoints that may be seen on the basis of MCM analysis to display certain features in common. There are different, cross-cutting

⁵¹ This software complements the *MC Mapper* interview software and was designed specifically to facilitate the analysis of MCM interview data.

ways to group participants into perspectives and, indeed, the participants were originally recruited on the basis of some provisional ideas in this regard (see earlier discussion in Section 4.3.2). However, the exploration of a variety of different perspectives is a central focus in MCM analysis.

Issues are groupings of criteria that may be seen on the basis of MCM results to display certain features in common. Issues are, in principle, potentially relevant across all perspectives, although in reality only some perspectives may actually invoke any given issue. Nevertheless, useful analysis can be conducted on the basis of how different types of issues are evaluated and defined across different perspectives. As with perspectives, there are different ways to group criteria into issues.

The process of defining issues or perspectives and grouping criteria or participants, respectively, is done through a relatively “inductive” process (Stirling and Mayer, 2001, p. 537) of ‘pattern-matching’ (Yin, 2003) and other qualitative analysis techniques. For example, criteria could be qualitatively analysed in several ways: *i*) in the way they are defined, *ii*) in the associated discussions around the definition of the criteria and *iii*) in the additional comments and insights as to the nature of the criterion made by the participant during the assessment process. Obviously criteria and participants could be grouped according to many different parameters.⁵² This was where the importance of the analysis being hypothesis-led comes to the fore. New hypotheses lead to new understandings of the data, which require new configurations and questions to be posed. This process continues until diminishing returns set in. Thus, the analysis, like the elicitation, is an iterative and reflexive process from start to finish.

4.5.3 Quantitative and qualitative analysis: towards heuristic understanding

For each hypothesis that is generated, a particular configuration of perspectives and issues is determined and analysis proceeds according to the summary table above. Various performance ranking charts are generated and qualitative and quantitative analyses proceed according to heuristic-based analysis of the performance ranking

⁵² In many cases there was some uncertainty as to how an individual criterion might be grouped according to the hypothesis being tested. In these cases, ‘uncertain’ criteria were either included or excluded from the analysis and two different sets of analyses performed. If the ‘uncertain’ criteria did not seem to affect the performance rankings in a significant manner, then they were usually included in the issue group. If they did affect the performance ranking, more detailed analysis was undertaken to determine why and how they were affecting option performance. A decision was made after this analysis was done from a more informed perspective as to the nature of the criteria and where it most appropriately was to be situated within the analysis.

charts. Where such heuristics indicate points of interest, further qualitative (or in some cases quantitative) analysis was conducted in order to gain insight and understanding into the underlying patterns. To aid in this process, performance ranking charts can display the quantitative data in several different ways. The most relevant charts for the analysis that will be presented in the main text of this thesis are underlined below. Detailed algorithms for each of the calculations used to generate the charts are given in Annex G.

- Rank means: these charts display option rankings as an interval (or ‘range’) between two averages: (i) all optimistic scores and (ii) all pessimistic scores. These intervals can be generated in two ways: 1) for a specified subset of interviews (a ‘perspective’) and criteria (an ‘issue’) or 2) for a specified subset of interviews and all issues together (thus indicating the overall ranking of the options in question). Generation and comparison of both sets of charts enables exploration of how and why option performance varies between different perspectives and under different issues .
- Rank extrema: these charts display the performance rankings for each option as an interval between the highest extreme optimistic score and the lowest extreme pessimistic score for a given set of interviews (a perspective) under all criteria.
- Mean interval uncertainty: these charts display the absolute scale of the difference between the mean optimistic and pessimistic scores, averaged for a given option over all relevant interviews (a perspective) and/or criteria (an issue).
- Mean ratio uncertainty: these charts display the same basic property of uncertainty, as that addressed in mean interval uncertainty (above). Here, though, it is expressed as the ratio of the absolute difference (as above) to the underlying values of the scoring ranges themselves. In other words, mean ratio uncertainty is calculated by taking the median of the pessimistic and optimistic scores and calculating the ratio between this and the corresponding interval uncertainty as defined above. Again, the calculation can be performed for any grouping of interviews (a perspective) and/or criteria (an issue).

Charts of ratio uncertainties can be used in conjunction with those for interval uncertainties to understand potential divergences of implications for the scale of uncertainty across perspectives, issues and options, depending on whether participants are held to be expressing this in absolute terms or in relation to the magnitudes of the scores themselves.

- Mean ambiguity: these charts display the scale of the differences between individuals in their option assessments. Such ambiguity is expressed here as the mean difference between optimistic scores and the mean difference between pessimistic scores for all interviews within a perspective under a set of criteria (issue).

Thus, whilst mean interval uncertainty displays *the scale of uncertainties* as expressed by individual participants, mean ambiguity displays *the scale of the differences* between different individuals included in the same perspective. It therefore reflects the *degree of collective disagreement* rather than individual, or average, uncertainty.

- *Median ambiguity*: this corresponds to mean ambiguity in that it reflects a measure of collective disagreement between individuals in a perspective. However, these charts display the average scale of the differences between the medians of each interview's option scores under a set of criteria (issue).
- *Issue weight extrema*: these charts display the highest and lowest criteria weightings expressed in a given set of interviews (a perspective) over different groups of criteria (an issue).
- *Issue mean weightings*: though not expressed as charts, these numerical values indicate the mean aggregate weightings in a given set of interviews (a perspective) over different groups of criteria (issues).

Each type of chart provides a way to analyse different features of the quantitative data and they feature in different ways in the analysis that follows in this thesis. We will now briefly comment on the issue of statistics within an MCM analysis, before concluding this chapter.

4.5.4 A note on statistics

MCM is a hybrid methodology, symmetrically incorporating quantitative and qualitative elements. However, if either were to be judged to take precedence, it would be the qualitative aspects – which address the reflexivity and openness that is a feature of both the interview and analysis process. While the quantitative features in an MCM analysis might in some ways be seen as complementary to statistical methods, the form of MCM data does not fit well with the strict parameters required in statistical analyses. Quantitative measures are used in MCM primarily as a heuristic to identify points of potential interest and provoke hypotheses, which in turn provide a guide for structured analysis of the qualitative material. Conclusions are drawn and tested on the basis of the full set of MCM data. Nevertheless, use of quantitative metrics and data in this methodology inevitably raises questions over the statistical robustness of some of the findings. Therefore, it is worth devoting some attention to considering this issue before proceeding to the empirical chapters.

The main point is that MCM is not designed, and has not previously been used, as a methodology that produces statistically significant findings. Nor does it need to be. As discussed above, MCM aims to capture the 'envelope' of key dimensions in a given policy area. Specifically, these include a range of perspectives, option assessments and ranks, criteria descriptions and weights, and expressions of uncertainty and ambiguity. This range of dimensions is more suitable to the type of analysis provided by MCM than aggregated parameters derived in statistical analysis would be (for example,

variance, standard deviation, confidence intervals, etc.). In addition, interviewee numbers in an MCM study are typically on the low side for high confidence in statistical generalisations, and the distribution of other data cannot be assumed to take the conventional normal form necessary for much statistical analysis. This is because we cannot assume that the main categories involved in MCM analysis (e.g., clusters of options, groups of issues, shared participant perspectives) display the homogeneity necessary for statistical generalisations. Moreover, to adopt such an approach would risk obscuring the crucial focus on *qualitative* differences and reflexively shifting framings *within* categories. Therefore, an MCM analysis is more comparable with qualitative, interpretive analysis such as that used in discursive or text-based research.

Given this, we can offer several points (positive and negative) about the positioning of MCM analysis in relation to statistical and qualitative approaches. First, in comparison with conventional quantitative methods, MCM is more sensitive to the participant's own framings and expressions. The interpretation of the 'results' are not solely reliant upon the interpretations of the analyst: the interviewee himself has the opportunity to amend or explain for his results so as to be consistent with his own point of view. This transparency and openness are also present in the MCM analysis process. An MCM analysis is more flexible and rigorous in terms of the constituting of the categories ('perspectives', 'issues', 'clusters'), which condition it. In other words, the categories are not conceived 'outside' the realm of the analysis and then imposed on the data as 'objective' analytical constructs, but instead are more reflexive in that they are continually interrogated in relation to the findings. Moreover, they are presented to the reader as subjective categories and open to judgement as such. Therefore, the dynamic and fluid nature of the analytical parameters becomes a strength of the analysis. It is one that enables the reader and analyst, alike, to become equally aware of the conditional nature of the findings and the basic data that underpins them.

Second, in comparison with other qualitative methods, MCM is able to offer a more detailed, transparent and verifiable approach to elicitation and analysis. Methodologically, the most direct comparators with MCM are qualitative, interpretive methods like semi-structured interviews or deliberative appraisal. In either case, the interpretations drawn by the analyst are not always reproducible, or arrived at in a transparent fashion. With MCM, the bases for conclusions are presented to the reader in the form of the ranking charts and tabular data, as well as the associated, *qualitative* evidence provided in the criteria definitions and weightings, option assessments and

other analytical ‘nuggets’. Thus, there is a clear ‘evidence trail’ which any reader could use to reproduce the findings (subject to use of the same interpretive conditions and assumptions as the analyst). In addition, and perhaps most crucially, though the number of individual viewpoints in an MCM study are perhaps not as numerous as would be required of conventional statistical methods, they are more numerous than many other qualitative methods. Thus, with appropriate caution in both analysis and elicitation (see below), we can be reasonably confident that the intensity and depth is strong in comparison to other qualitative methods.

Third, and finally, alongside its strengths we should also point out some of the associated weaknesses of MCM. The principal danger in any MCM analysis is that of over-interpretation. In order to minimise this, this study adopts principles of disciplinary rigour in MCM established and developed in previous studies (Stirling and Mayer, 2001; Davies, et. al, 2003; Davies and Burgess, 2004; McDowall and Eames, 2007). Crucially, the findings presented in the following chapters are based only on those ‘signals’ and patterns that are the most prominent and unqualified. In each case, the full relevant data are reproduced alongside the point being made so as to allow contrasting and critical reflections. Where qualifications do exist, we point out and actively explore alternative explanations. This is done through the testing of alternative hypotheses, internal triangulation between MCM parameters (ranking patterns, criteria definitions, weightings), and the testing of uncertainty and ambiguity. Therefore, the conclusions made are open to judgement of plausibility by the reader. Although it is possible that separate subsequent research might identify ways in which certain specially-configured statistical analytic techniques might be integrated with some aspects of MCM (see conclusions), such a methodological innovation lies beyond the scope of the present study (and the entire contemporary MCM literature as a whole). Against this, we can say with some degree of confidence, that when judged against more conventional quantitative and qualitative methods, the findings and conclusions of an MCM study grounded in analytical and empirical rigour.

4.6 Conclusion

It should now be apparent that the methodology underpinning this thesis is a theoretically and empirically demanding construct in its own right. The amount of data that is generated in one MCM interview, let alone 57, is enormous and to a certain

extent unwieldy. Thus, the findings that are presented in this thesis do not represent the full breadth and depth of the analysis conducted. For example, identifying the perspectives and issues which form the basis of the analysis were based upon the testing of countless hypotheses, groupings and orderings of data, in addition to detailed qualitative and quantitative analyses. The findings used to support the main hypotheses of this thesis and to answer the central research questions only reflect a small proportion of the richness of the data collected.

Nevertheless, the following pages will cover broad analytical ground. The next chapter is the first of four empirically-grounded chapters. It reviews a subset of the formal policy literature on hESC research in the US and the UK, and an analytical framework for the findings is presented. Chapters 6 and 7 present two sets of empirical findings from the 57 MCM interviews, the first according to national groups of stakeholder perspectives in the US and UK and the second comparing perspectives of policy actor groups as defined within the analysis by shared points of view. Chapter 8 draws the policy- and interview-based empirical findings and the theoretical strands together.

5. Good governance of human embryonic stem cell research: a review of the policy literature

5.1 *Introduction*

This thesis is concerned with whether divergent stakeholder perspectives on good governance for human embryonic stem cell (hESC) research are, first, discernible within different socio-political and national contexts and, second, whether systematic patterns between different perspectives emerge from this examination. Previous chapters have reviewed the scientific and country-specific policy histories in the field of hESC research and theoretical concepts of ‘good governance’. What has not yet been accomplished, though, is an integration of these two strands into an account of how good governance for hESC research is constructed by policy actors in the UK and the US. In order to address this, we must look to wider literatures. This will allow us to become familiar with the variety of technological framings, analytical viewpoints, social issues and cultural dynamics that bear upon the hypotheses of this thesis.

This chapter will begin the process by analysing how good governance is characterised and interpreted within a subset of the formal policy literature on hESC research in the US and the UK. It aims to identify systematic patterns in the ways in which governance is characterised in these literatures and, from this, determine how perspectives on ‘good’ governance are constituted within different socio-political realms. The significance of this chapter to the overall thesis, then, is to establish a ‘baseline’ against which the views on good governance uncovered in the empirical work of the thesis can be compared. The analytical policy literature review presented here amounts to a ‘top-down’ account of good governance, which aims to deconstruct notions of good governance as they are ‘officially’ discussed in a policy context. This is in contrast to the empirical results and analytical findings that will be discussed in later chapters and amount more to a ‘bottom-up’ account of good governance.

The structure of this chapter is as follows: it will first build on the governance theories introduced in Chapter 3 in order to ground good governance in the context of biomedical technologies. It will then present a subset of the core policy literature in the area of hESC research. Overarching themes of good governance are identified within these literatures and are used to structure the analysis. Evidence for the interpretation of

good governance within each theme is given and additional support is identified in wider academic and stakeholder literatures. The chapter will conclude by reviewing the themes of good governance and any variations uncovered between the US and the UK.

5.2 *The problem of biotechnology governance*

5.2.1 Overview

An aim of the theoretical chapter on governance (Chapter 3) was to “understand how governance in a context of risk and uncertainty is affected by, and might respond to, the challenges of ‘new governance’” that are posed by advances in the biosciences (specifically) and the associated risks and uncertainties (of many types) associated with them. The chapter reviewed how various understandings of these challenges are arrived at by governments and policy actors. These understandings are never straightforward and can hinge on many factors and competing priorities. For example, the notion of science as the seemingly objective bastion of certainty (as invoked by ‘sound science’ rhetorics in policy making) has been shown to be something that can vary depending on how it is constructed (Latour and Woolgar, 1979). Competing values and subjective experiences shape the ways in which ‘scientific facts’ are presented and interpreted (Levidow and Carr, 1997; Wynne, 2001). This all serves to underscore the importance of understanding the social, technological, economic, political and cultural components of emerging areas of science and technology. This has long been known to scholars of STS, who argue that with the development of new technologies comes a variety of influential interactions between technological and social processes. The nature of these interactions plays an important role in influencing technological development and render it “a fundamentally social process open to sociological analysis” (Martin, 2001, p. 195; see also, Bijker et al., 1987; Bijker, 1995; Williams and Edge, 1996).

This analysis can take many shapes and the relative importance and influence of the related social processes, be they political, economic, cultural and so on, will vary according to the nature of the technology being discussed and the nature of risk and uncertainty associated with it. This recalls Beck’s thesis that risk is a culturally embedded phenomenon (Beck, 1992). He argues that the nature of risk in today’s society is characterised by the continued introduction of new technologies. It is in appreciating how such a conception of the (rather reflexive) relationship between risk and technology comes to exist that we find resonance with the ideas in this research.

From here, the question becomes one of making the link from technological risks more generally, to medical biotechnologies – and stem cell research – in particular. In this task, it is not the intention to adopt Beck’s theoretical framework, but rather to appreciate the relatively uncertain context in which new biomedical technologies emerge and the associated implications for governance. Many have commented on the fact that new technologies emerging from advances in the biosciences are particularly pervaded, and corresponding governance issues particularly influenced, by entangled cultural and social values. It is the ‘biological’ nature of these technologies that gives the distinctive character to what some have termed ‘biopolitics’ (Jasanoff, 2005), as they pose difficult questions about “the character of our human/nonhuman identify” (Brown and Webster, 2004, p. 2). Weale (2001) argues that it is these characteristics that introduce difficult policy problems, particularly when it comes to assessing how scientific advice and public input might feed into the policy-making process. In this, it is hard to disagree with Weale’s sentiment that “incommensurable values produce complex political problems” (2001, p. 420). For the present authors, though, the key question lies not just in understanding *how* these complex problems are produced, but also in how they *ought* to be addressed.

One of the aims of this thesis is to draw out the implications of these issues in a way that will enable us to make an empirically-based contribution to knowledge of relevance to a variety of different literatures, as well as a normative contribution of potential relevance to policy-making. The following sections will demonstrate that there are different ways of interpreting what policy actors believe good governance of hESC research should look like and the components it might entail. Thus, the review in this chapter amounts to a systematic examination of key perspectives on ‘good governance’ of hESC research as they emerge from the national policy documents.

5.2.2 Good governance of hESC research: reviewing the policy literature

To a certain extent, broader changes and new modes of governance are already emerging to deal with the increasing pressures that society and governments are faced with in the context of scientific and technological advances in the biosciences. This can be seen through the rise of ethics committees as bodies of expertise (Levidow and Carr, 1997; Wynne, 2001); public participation experiments in deliberative democracy (Rayner, 2003; Davies and Burgess, 2004); changes in the nature of political discourse

(Brown and Michael, 2002); and the emergence of a global “moral economy” of bioethics (Salter and Salter, 2007; Gottweis et al., 2009). As it becomes clear that there are many ways in which governments and publics try to address conflicting values, we also see that there is no straightforward answer as to which modes and approaches will be most appropriate, and under which circumstances.⁵³ Scholars and stakeholders would argue that a variety of factors must be brought into consideration such as the acknowledgement of social values and wider cultural risks outside the ‘technical’ ones, increasing openness and transparency, a greater inclusion of broader ‘publics’, and changes to the nature and content of the policy debates. The relative ‘amounts’ of each of these in different approaches will vary as they may privilege some interests over others, or favour particular political ideologies.

One of the first places one might expect to see evidence of this is in the official policy literature itself. Within each country, core policy documents can be found which form the basis for policy development. These documents review the issues, draw conclusions and make recommendations for policy-making. Since these recommendations are underpinned by a review of the relevant social, scientific, medical, political, legal and/or ethical issues, we can reasonably expect they may be interpreted and analysed for the views on good governance that are being expressed by the government or official body that produced the report. As introduced in the previous chapter,⁵⁴ six primary policy documents (three each for the UK and US) were identified and systematically reviewed for content with an eye to identifying common themes and rationales of good governance specifically in relation to hESC research. The documents were selected according to the following selection criteria: *i*) they were produced after the announcement of the derivation of the first human embryonic stem cell line in 1998,⁵⁵ *ii*) they are relevant at a national level,⁵⁶ *iii*) they focus on a range of issues specifically relevant to hESC research and *iv*) they can generally be considered to be of primary importance as a basis or formal rationale for policy initiatives within each national context. A brief summary of each of the documents reviewed is discussed in Table 5.1 below.

⁵³ See the discussions in Chapter 3 for additional detail on particular ‘modes’ or ‘approaches’.

⁵⁴ See the discussion in Chapter 4, p. 60-61.

⁵⁵ It should be noted that no documents published prior to 1998 were included in the review. This is because the first scientific breakthroughs in the production of an hESC line were announced in 1998. Though many more general issues bearing on human embryo research were discussed in both countries going back to the 1970s, the specific governance issues raised by human embryonic *stem cell* research were focussed on in more depth and brought to the fore after the 1998 breakthroughs.

⁵⁶ As opposed, for example, to covering specific regions of the UK or individual states in the US.

Table 5.1: Summary of ‘core’ formal policy documents

US Policy Documents	
<i>Ethical Issues in Stem Cell Research (1999)</i> (hereafter referred to as the NBAC report)	This report was requested by President Clinton from his National Bioethics Advisory Council (NBAC). Clinton requested that the Council examine the implications of recent developments in hESC science following the development of the first hESC line. It is one of the first official US government policy documents to review the scientific, medical, ethical, legal and social issues at stake. The report makes recommendations on how and under what circumstances hESC research might be supported in the US.
<i>Monitoring Stem Cell Research (2004)</i> (hereafter referred to as the PCBE report)	This report was produced by the President's Council on Bioethics (PCBE) and was officially requested by President George W. Bush in 2002. Its aim was to report on developments in the field of stem cell research since the President's policy for hESC research was implemented in 2001. The report did not contain any policy recommendations, but rather aimed to “shed light” on the current scientific, ethical, legal and medical state of the field.
<i>Guidelines for Human Embryonic Stem Cell Research (2005)</i> (hereafter referred to as the NAS Guidelines)	The US National Academy of Sciences (NAS) is not an official executive body of the US government, but it is seen as the de-facto advisor to the government on a variety of scientific and related policy issues. In the absence of any national guidelines on hESC research, and in response to requests from the scientific community, the NAS sought private funding for a blue-ribbon commission to develop voluntary guidelines on the conduct and oversight of hESC research. These have served as ‘unofficial’ official guidelines for hESC research in the US and provide important insights into the views of the national scientific community on issues of good governance.
UK Policy Documents	
<i>Chief Medical Officer's Report: Medical Progress with Responsibility (2000)</i> (hereafter referred to as the Donaldson Report)	This report was produced by an Expert Group set up by the Department of Health and chaired by the Chief Medical Officer, Sir Liam Donaldson. Its remit was to advise the government on whether research using embryos should be permitted and what the associated scientific, technical, therapeutic, and regulatory issues might be if it was allowed to proceed. It is one of the first official government reports released after the 1998 development of the first human embryonic stem cell lines and it was in light of the recommendations offered in this report that the UK Government introduced extended regulations for the purposes of embryo research.
<i>Stem Cell Research: Report from the Select Committee (2002)</i> (hereafter referred to as the Report from the Select Committee)	In 2001 the UK Parliament passed the Human Fertilisation and Embryology (Research Purposes) Regulations, which extended the regulations for which research on human embryos is permitted under a license from the HFEA. In light of these new regulations, the House of Lords Science and Technology Select Committee was asked to “consider and report on the issues connected with human cloning and stem cell research” that arose from the new regulations. The report comprehensively addresses the issues related to stem cell research and makes recommendations on how the government should proceed with future legislation and governance.
<i>Human Reproductive Technologies and the Law (2005)</i> (hereafter referred to as the HRT and the Law report)	This report was produced by the UK House of Commons Science and Technology Committee in 2005. It marked the beginning of a four-year review of both the HFE Act and the ‘state-of-the-art’ of human reproductive technologies in the UK. It assesses whether advances in human reproductive technologies have raised new social, legal or scientific issues that would require revisions to the original legislation. Many concepts first introduced in this report are reflected throughout policy documents issued both by Parliament and the UK Government until November 2008, when the final version of the Human Fertilisation and Embryology Bill 2008 (essentially a revision of the Human Fertilisation and Embryology Act of 1990) was passed.

After identification as a ‘core’ policy document, each report was reviewed systematically and coded⁵⁷ for organisational structure, content and thematic attention paid to different governance issues related to hESC research.⁵⁸ However, conducting such an analysis on a narrow range of documents could lead risk selecting out some documents that may introduce a different perspective, and thus lead to a different set of conclusions. As a means to appraise and mitigate this risk, ‘the next most suitable’ policy document(s) were considered according to the same analytical framework. This step also served to check the basis for prioritisation of the core documents.

In the UK, the next most suitable policy document was the ‘UK Stem Cell Initiative’ report, which was published in 2005 and presented a future investment strategy for stem cell research in the UK. If followed, it was claimed it would be capable of enabling the UK scientific community to become world leaders in stem cell research. The strategy focuses largely on commercialisation and investment and so is skewed in its presentation of relevant governance issues. Nevertheless, it covers similar themes to those discussed below and no significant differences in content were discerned. The next document to be considered was a workshop report on stem cell therapy by the Nuffield Council on Bioethics. This document was ruled out primarily because it focuses specifically on stem cell therapies and does not consider many issues related to the fundamental nature of hESC research. In addition, the document was a summary report of a workshop, and so only covers material from the day.

In the US, the next most suitable policy document for inclusion was a report of the National Research Council published in 2002 and entitled ‘Stem Cells and the Future of Regenerative Medicine’. This publication was the report of a workshop convened by the NAS that brought together several leading stem cell scientists, philosophers, ethicists and legal scholars. The report did not raise new or significantly different points from those in the three other US documents. In addition, it was a workshop report and so only covered material discussed on the day.

⁵⁷ For a discussion of the methodology employed in this respect, see p. 60-61 of Chapter 4. As pointed out there, 12 policy documents were originally considered and this was narrowed down to the six core documents presented in this chapter. The text below describes the steps taken to mitigate the risk that the ‘next most important’ document in each country should not also have been included in the analysis.

⁵⁸ The majority of the documents are specifically concerned with stem cell research, but one of the documents, *Human Reproductive Technologies and the Law*, covers the entire field of human reproductive technologies that fall within the purview of the HFE Act. Thus, the report covers embryo and hESC research, but is not exclusively dedicated to hESC research, as is the case in the other policy documents.

In the analysis of the core documents, attention was paid not only to *which* issues were given attention, but also to *how* they were discussed, the *particular problems* identified, the *solutions* suggested and the *implications* of all of this for good governance. It is on the basis of broad similarities within the way the issues are presented that four themes of good governance are identified as featuring in the majority of the documents. The fact these four themes do emerge suggest they might be useful as an overarching framework within which we can identify systematic patterns, points of comparison and areas of synergy throughout the analysis. Thus, using this framework, we can build an understanding of the ways in which governance is constructed, framed and interpreted as ‘good’, and how this may (or may not) differ between the two countries. The themes of good governance (indicated in bold) and associated sub-themes are:

- ***Scientific and technological issues in hESC research***, with sub-themes of scientific ‘outcomes’ (e.g. autonomous research environments or therapeutic aims); research support; and technological development.
- ***Ethical issues in hESC research***, with sub-themes concerning research principles of conduct and the moral status of the embryo.
- ***Institutions and instruments for hESC research***, with sub-themes of policies for oversight and funding; policies for regulatory activities; and qualities of deliberation (inputs and interactions of publics and experts).
- ***Socially and culturally-based aspects of good governance***, with sub-themes of the maintenance of policy continuity, and the bases of trust and legitimacy.

Table 5.2 below provides an interpretive summary of the extent to which each report covers issues within each of the broader themes. The narrative indications of the different shadings in the table are only meant to provide an illustrative overview, not something that has been comprehensively ‘calculated’ or additive values. Nonetheless, they present a comparable picture across all the core documents, themes and cases study contexts taken as a whole.

Table 5.2: Themes and issues in good governance of hESC research⁵⁹

Theme		Advances scientific & technological outcomes & addresses related issues in hESC research				Encourages moral & ethical awareness for hESC research		Establishes appropriate institutions & instruments for hESC research			Identifiable social & cultural bases of good governance	
Sub-theme		Outcomes: Scientific autonomy	Outcomes: Therapeutic Goals	Research support processes	Perceptions of risk (technological or social)	Principles of conduct	Moral status of embryo	Policy approaches: Oversight and funding	Policy approaches: Regulatory activities	Qualities of deliberative activities: Publics & experts	Bases of trust and legitimacy	Maintaining continuity
US: NBAC Report (1999)												
US: PCBE Report (2004)												
US: NAS Guidelines (2005)												
UK: CMO Report (2000)												
UK: House of Lords Report (2002)												
UK: HRT and the Law (2005)												

Shading Key

	Sub-theme is extensively covered and is central to the perspectives on good governance
	Sub-theme is reasonably covered and features prominently in perspectives on good governance
	Sub-theme is mentioned, but is not a prominent feature of the perspectives on good governance
	Sub-theme may be mentioned within literature, but does not feature in perspectives on good governance

Within each of these themes and sub-themes many features of good governance of hESC research are identified and discussed. However, presenting the features in such a structured, schematic way invites an array of possible criticisms, such as oversimplification of the complex interactions among many of the governance processes represented or cultural contingencies upon which they may rest. Indeed, such criticisms resonate strongly with the thrust of this present thesis and the sympathies of the authors. If we were to treat each theme and sub-theme as if in a ‘vacuum’, it would be in conflict with the broad socio-political definition of governance adopted for this thesis and the emphasis on the interactions and feedbacks between various processes, networks and

⁵⁹ See discussion in the methodology chapter, p. 60-61, for detail as to how the analysis of the documents occurred. As indicated there, recordings were made as to the relative ‘coverage’ of each theme within the policy documents. From this basis, determinations of shading were made which reflected relative levels of coverage as indicated by the key above.

actors. Rather, by grouping the perspectives that emerged from the policy literature into similar sub-themes and, then, overarching themes, we are able to develop a type of analytical tool with which we can systematically unpack and understand how extant, individual perspectives on good governance are articulated and assembled (or re-assembled) within the policy literature chosen here. It is hoped this will enable a richer characterisation and interpretation of good governance within the different national, political and cultural domains that are being explored for this thesis.

With this in mind, the simple presentation of the sub-themes and the respective coverage of each within the academic literature seems to indicate that each is reasonably prominent in its own right. This underscores the suitability of the analytical framework for identifying not only areas of, but perspectives on, good governance. Each policy document covers, at least to a certain extent, the majority of the sub-themes identified above, it not all of them. Intriguingly, an initial glance indicates that there do seem to be systematic differences in emphasis across the US and the UK, such as in the framing of scientific outcomes, the moral status of the embryo and the nature of oversight policies. The implications of this and other analytical points of comparison will be explored throughout the remainder of this chapter.

5.3 Advancing scientific and technological outcomes; Addressing related issues

5.3.1 Overview

This section will consider how the six policy documents address scientific and technological issues in the context of good governance. It will first compare the ways in which the literature highlights the scientific nature and trajectory of hESC research, and thus reflects different framings of desired scientific outcomes. It will then go on to discuss the mechanisms and processes that should be in place to support the realisation of these outcomes. Finally, it will consider the ways in which the literature frames perceptions of technological, social and cultural risk. As was alluded to above (and will continue to be pointed to throughout this chapter), it is precisely *which* issues are discussed, *how* and by *whom* they are discussed, and under *what* conditions the discussion takes place that are of interest to our analysis. Thus, the role of *framing*⁶⁰ in

⁶⁰ See discussion in Chapter 3, p. 41.

the analysis of good governance will be a recurring theme within the work presented below.

5.3.2 Outcomes: scientific autonomy and therapeutic goals

The ‘trajectory’ (Williams and Edge, 1996) of the field of hESC research is presented differently and to different effect in the US and UK policy literatures. This has important implications for the framing of scientific outcomes within the overall narrative of good governance. Within the UK policy literature analysed below, there seems to be a greater emphasis on the therapeutic outcomes of hESC research. When the science is discussed in the UK policy documents, it tends to be framed in terms of current problems with medical technology and/or incurable diseases and the potential that stem cell technology has to overcome this. Within the US policy literature, the emphasis seems to be on scientific autonomy as a key enabler of good scientific outcomes, be they therapeutic- or basic research-oriented. In other words, there seems to be more of a tendency to present the issues as a matter of preserving scientific autonomy so that the scientists are free to pursue multiple paths towards ‘successful’ scientific outcomes. These ‘successes’, then, are defined by the scientists themselves and may include therapeutic outcomes, but may also simply broaden our understanding of basic scientific knowledge and biological development. The evidence for each of these claims is discussed in turn below, beginning with the UK.

In the 2000 Donaldson Report, the chapter reviewing the scientific background of hESC research begins with a “simple overview of the complex techniques which could yield cells capable of repairing diseased or damaged organs” (DoH, 2000, p. 16). It then goes on to outline the problems with organ transplantation in the UK, thereby establishing from the start a medical and public health problem for which stem cell technology could be a solution.

A new prospect of widely available human tissue that is biologically compatible with the recipient has now been opened up by greater scientific understanding of the growth and development of animal and human cells (Ibid, p. 17).

The report goes even further in its claims of the promise of stem cell technologies, stating on the next page that “the scope for stem cell therapy in the future could be enormous” (Ibid, p. 18). The reader is left with little doubt as to why this area of research is worth being pursued. Similarly, in the Stem Cell Research report from the House of Lords Select Committee, the report immediately addresses (after a brief

introductory section) the potential of stem cells in developing new medical therapies. In the first paragraph of this section, the committee lists a range of degenerative diseases that “affect millions of people in the United Kingdom alone” and claims that “stem cell treatments, unlike most conventional drug treatments, have the potential to become a life-long cure” (House of Lords Select Committee, 2002, p. 11).

In both of these examples there is a great amount of certainty with which it is claimed that hESC science will one day lead to treatments for a variety of diseases and solutions to public health problems. This is especially remarkable given that both of these reports were published less than five years after the first hESC lines were developed. Nevertheless, in the case of the UK policy documents, the framing of hESC research in terms of public health and medical technology solutions is clear.

In the US policy literature, hESC research is first described in historical terms. The field of stem cell research, and thereby hESC research, is presented as one that scientists have been working in for many years and has been long recognised for its potential to explain many developmental, biological and disease-specific questions. By presenting the science in a detailed and technical way with a focus on its history, the policy documents seem to be suggesting there is a particular importance to the preservation of scientific autonomy as an aspect of good governance. This will lead to the advancement of scientific knowledge, as history has already proven, and perhaps one day to therapeutic and technological developments. However, it is for the scientists, not policymakers, to determine how and when this might happen.

The NBAC report only mentions the therapeutic potential of hESC research after accounts of the past and current state of hESC research are given. When any therapeutic potentials are mentioned, the tone seems one of exploration, rather than direct intent:

this research might, for example, lead to the discovery of new ways to treat a variety of conditions...and would build on investigations conducted over the last decade, in which laboratory animals have been used to determine whether ES cells can be used to re-establish tissue in an adult organism (NBAC, 1999, p. 8).

The passage refers specifically to examples of how science ‘builds’ on previous investigations. This leaves one feeling as though possible treatments and therapies are simply a natural progression of yet another field of scientific inquiry. This reinforces the idea that hESC research is not a new area of science, but rather, one where new findings, such as the derivation of hESC lines in 1998, are merely the result of a natural progression of scientific inquiry.

The NAS Guidelines also reflect the notion that respect for scientific autonomy is an important part of good governance. Like the NBAC report, hESC research is framed so as to establish its legitimacy as a long-standing area of scientific inquiry. Desired scientific outcomes are described in reference to the research merits of hESC research itself. Though it does point out in the executive summary and introductory chapters that it is the “dual capacity of stem cells for self-renewal and for differentiation into particular types of cells and tissues [that] offers great potential for regenerative medicine” (NRC and IOM, 2005, p. 15), this comes across as a tangential comment. Whereas in the UK’s Donaldson Report, hESC research was introduced by discussing the problems with medical transplant technology, in the NAS Guidelines it is introduced via a detailed scientific account of the history of the field. Only after this are the prospects for its application discussed. Thus, we see a similar pattern to the NBAC report where the scientific background is presented in great detail and it is only within this detail that references are made to therapeutic and technological prospects.

Though the PCBE report was produced under the presidency of George W. Bush (whose restrictive funding policy on human embryonic stem cell research was reviewed in Chapter 2), we still find a similar framing of hESC research. The report gives a detailed account of the science of stem cell research in the final chapter, but it refers throughout the text to several appendices which go into great detail about various types of stem cell research, the historical development of the field, and possible therapeutic applications of both adult and human embryonic stem cells. It is the case that more caution is present within the text about the ‘hype’ surrounding hESC research, but this could be due to the policy context under which the report was produced. In other words, though scientific autonomy frames the discussion of the science, the tone does suggest that autonomy does not equate to free reign.

To sum up, the point is not to claim that the US policy literature is unconcerned with the therapeutic benefits of hESC research, but rather that the discussion emphasises how well the science has developed *on its own*. Good governance, then, should seek to preserve this autonomous nature. This is in contrast to an emphasis on the future therapeutic outcomes of hESC research in the UK. The implications for good governance here are the need to actively support this type of research because of the medical benefits to society which may result.

5.3.3 Issues: Research support processes

The next area to consider within this theme is the ways in which it is argued that the realisation of the scientific outcomes should be facilitated and the research enterprise supported. The discussion below will highlight how the perspectives on this element of good governance complement and further reinforce the framing of hESC research and related scientific outcomes.

A key feature of research support in each country is about standardisation of research practice. Standardisation is believed to be necessary to advance the research and move towards therapeutic products (Harvey, 2009), facilitate researcher collaboration and sharing of information (Baker, 2008), promote a philosophy of ‘governance-by-standards’ (Webster and Eriksson, 2008) and manage uncertainty around new regenerative medicine technologies (Gottweis, et al, 2009). The argument for establishing these links is made differently in the policy documents of each country. In the UK policy documents, good governance is concerned with how best to facilitate the realisation of desired therapeutic outcomes through *government-mediated* mechanisms of support. In the US documents, processes for research support are less about direct interventions in the science and more about the establishment of indirect, enabling frameworks within which the science can autonomously develop.

The respective processes of research support in the policy documents reinforce the framings of hESC research discussed above. According to one UK policy document, the aim is to ensure “that legitimate medical and scientific applications of human reproductive technologies can continue to flourish” (DoH, 2007, p. 1). More to the point, though, it is argued that the science can move towards therapeutic benefits because of “the enabling and consistent regulatory environment”, which “is currently one of the strongest assets to UK stem cell research” (UK Stem Cell Initiative, 2005, p. 43). This ‘enabling’ regulatory environment is believed to be a crucial aspect of good research support processes and is mentioned in all three UK policy documents. Specific processes that result from direct government support include: the establishment of a national stem cell bank; the writing into legislation of the need for basic research; and the balancing of regulatory oversight with an open commercial environment.

Standardisation is also discussed in the US-based policy literature, but in a way that emphasises harmonisation of indirect oversight practices, not centrally managed government initiatives. The emphasis on harmonised oversight reinforces the historical framing of the science. Harmonisation has in the past facilitated autonomous research

activities, while still ensuring the responsible and ethical conduct of research. It is argued in the NAS Guidelines that the “patchwork” of regulations in the US serves to undermine not only the progress of the research, but also the “integrity” of all types of hESC research being pursued. “Some standard protections may be lacking and the implementation of protections is almost certainly not uniform throughout the country” (NRC and IOM, 2005, p. 19). The implication is two-fold. First, the lack of a harmonised ‘space’ for science might result in “less efficient and less powerful science” (Webb, 2007). It also suggests that standardisation as a feature of good governance is especially important to ensuring scientific integrity in the eyes of the public.

Thus, in both country’s policy documents, the nuances in the perspectives on good governance for research support lie both in the references to ideas about the scientific trajectories as discussed previously and the way this links to ‘responsibility’. With the UK policy literature there is a greater emphasis on standardisation to actively facilitate and manage aspects of the science (whilst ensuring it is done in a responsible manner), whereas within the US policy literature the emphasis is firstly on standardisation to foster scientific autonomy so that the responsible conduct of the science can be ensured.

5.3.4 Issues: Perceptions of risk (technological or social)

As we have seen in the analysis so far, the nature of hESC research means that the potential benefits of technologies that may arise from it are part and parcel of discussing related components of good governance. With this comes a discussion of the perceptions of technological, social and cultural risk associated with developments in hESC research. In the previous chapter the ways in which risk is determined and factored into policy decisions was shown to be subject to different framings that, themselves, are constituted by different perceptions and values. Thus, alternate framings of risk can affect regulatory, or governance, choices. Examples arise in the case of genetic testing in the US and the UK (Parthasarathy, 2004, 2005), or in consideration of future regulatory regimes for hESC therapies (Liddell and Wallace, 2005).

In both sets of policy literatures from the US and the UK, risks are presented and framed in one of two contexts: first, in the therapeutic context, as technical and safety risks and, second in an ethical context, as social and cultural risks. In the former, the main safety issues are around possible therapeutic applications of stem cell research technologies. Each set of national policy documents emphasises the need for future

governance frameworks to ensure patient safety, incorporate informed consent mechanisms and work with or within existing mechanisms of regulatory oversight for drugs and clinical therapies. These elements are addressed fairly similarly in each set of national policy documents.

However, it is in discussing the social and cultural risks posed by the technologies implicated in embryo research that we see differences in the framing of risk emerge. These risks are tied to fundamental ethical and moral questions about embryo research, issues which are more fully discussed in the next section. What is noteworthy for the discussion here is that in presenting the ‘social’ risks of embryo research, the framing of public health and therapeutic outcomes of the science in the case of the UK and scientific autonomy in the case of the US are seen. For example, in discussing the special status of the embryo in the Stem Cell Research Report, the House of Lords Science and Technology Select Committee addresses the issue of respect for persons and concludes:

respect may take the form of developing treatments for serious degenerative diseases, and there can be few causes more worthwhile than to relieve the suffering caused by these diseases...It would be wrong not to seek therapies for such diseases, which necessarily involves undertaking the fundamental research that may make those therapies possible (House of Lords Select Committee, 2002, p. 22).

The Donaldson report uses even starker language when describing the issue of using leftover embryos from infertility treatment in stem cell research, arguing that “the only options at this stage are to let the embryos perish or to use them... as part of the effort to enhance future fertility treatment and human lives” (DoH, 2000, p. 38). This sends a strong signal that social risk of hESC research does not lie with the pursuit of the research, but rather with the *failure* to pursue the research.

Conversely, in the case of the US policy literature, social risk seems to lie with how, or whether, the research is conducted. In the NAS and NBAC documents, the risks posed by the technologies and scientific practices of hESC research are presented as risks to scientific autonomy and the freedom to pursue research. In the case of the PCBE document, which was produced under a policy environment less favourable towards hESC research, the social risk lies more heavily with the use of embryos in research and the threats to human dignity that this poses.

These differences in the characterisation and framing of social risk within each set of national policy documents illustrate that in each country the social risks of the technology are framed in a manner that correlates with previous perceptions of the types

of activities or mechanisms good governance would help achieve. The next section addresses perspectives on good governance in relation to ethical and moral issues in hESC research, beginning first with perspectives on the moral status of the embryo, and second discussing how this status might be protected through the ethical principles of research practice.

5.4 *Encourages moral and ethical awareness*

5.4.1 Overview

Discussions of hESC research in the wider literature often begin with the status of the embryo. However, the moral and ethical principles wrapped up with hESC research and policy extend well beyond these considerations, to issues such as cultural pluralism, equity, justice and ethical conduct of the research in the laboratory setting. This section will look first at the wider ethical issues relating to the conduct of hESC research. It will then review the framing of the moral status of the human embryo in the policy documents. We will argue that the ways in which the embryo is presented has important implications not only for the structure of the policy debates (Kirejczyk, 1999), but also for emerging perspectives on good governance.

While, overall, there is little difference in the types of ethical issues developed in each set of policy documents, what differs between the two countries are the ways in which it is argued that good governance should address these ethical issues. In the UK, it appears that good governance under this theme emerges through the institutions of law and regulation, such as the enforcement of ethical conduct and the preservation of the special status of the embryo through a legislative framework. Good governance, then, is an attempt to balance the ethics and the science. In the US good governance tends to be characterised by a confidence in the system of federal funding to uphold ethical principles of research. This reinforces the respect for scientific and market autonomy (in the absence of formal legislation), and places trust in the scientific community to police itself. However, what is notably absent from the US policy documents is a consistent treatment of the embryo. This leaves it an open question as to how good governance will (or can) address the status of the embryo. What is important to bear in mind throughout the analysis, though, is the centrality with which the ethical and moral issues seem to frame perspectives on good governance more widely.

5.4.2 Ethical principles underpinning research conduct

In an area as entangled with ethical issues as hESC research, it is not surprising that there is a great deal of concern and discussion over the ethical *conduct* of the research and the extent to which the establishment of *appropriate* ethical conduct will help to mitigate a variety of perceived social and cultural threats posed by the research. These threats include an affront to moral values by destroying the early embryo for research; the related danger of “instrumentalization” of the embryo through such research practices (NBAC, 1999), including the exploitation of woman; and the threat of human reproductive cloning becoming a scientific possibility through continued advances in research technology (PCBE, 2004; NRC and IOM, 2005). With some exceptions in the level of detail afforded to each, it is fair to say that each threat is covered within the respective national policy literatures. However, there are differences between the national policy documents in the mechanisms through which it is argued that appropriate and ethical research conduct might mitigate these threats.

In the UK policy literature, the arguments employed in the Warnock Report (Warnock, 1985) about the acceptability of embryo research are always referred to first when discussing the ethical principles that must underpin hESC research.⁶¹ However, it is not just the principles that are referred to, but also the process through which they were developed. There were extensive deliberations, periods of reflective thought and public consultations undertaken by the Warnock Committee. The fact that the ethical principles rest upon such broad-based deliberative processes is always pointed to as illustrative of the legitimate basis on which the principles rest. Moreover, the central role the report plays in providing the basis for the HFE Act of 1990 and all other regulations and legislation, further reinforces this legitimacy and encourages acceptance of the Committee’s findings.

In terms of the perspective on good governance that emerges from the UK policy literature, it seems that there is a considerable emphasis on ensuring ethical conduct through a ‘hands-on’ relationship between the regulated and the regulator. Such a relationship (it is argued) will assure public confidence in the fact that the research is being conducted in a responsible manner. Thus, in arguing for why the system of oversight should continue in its current form, the UK Government has argued that it has: “engendered *public confidence* in the *ethical development* and use of human

⁶¹ As the Warnock Report was the main locus of deliberation on the moral acceptability of embryo research in the first instance, it will be discussed in greater detail in the next section.

reproductive technologies”; “allowed medical and scientific progress to *flourish* within appropriate *safeguards*”; and “achieved *consistency* across the country” (emphasis added, DoH, 2005a, p. 13). Each point italicised above reflects important notions of good governance that the regulatory system achieves.

Two additional points are worth pointing out that reflect subtle variations in the perspective on good governance emerging from the UK policy literature referenced above. First, it is not just ethical conduct of the research, but ethical ‘development’ that is referred to. This implies a continuous appraisal of the ethical situation as the science develops is an important component of good governance. Second, the statement suggests that medical progress has flourished because of the safeguards in place. This further reinforces the notion that good governance assures ethical principles are upheld, as well as facilitating scientific and medical advances.

Like the UK policy literature, some of the US policy literature seems in favour of continuing existing systems of oversight in order to assure ethical conduct of hESC research. Unlike the UK literature, however, the perspectives on good governance that emerge from the US policy literature seem aimed at reinforcing ideas about scientific autonomy. The argument emphasises how ethical conduct already occurs through existing mechanisms within the system of federal research funding and the required local and national Institutional Review Board (IRB) procedures. With the exception of a few small additions, then, the NAS and NBAC reports suggest adoption of a rather similar governance system for hESC research to the one that has existed for many years for all of biomedical research.⁶²

This might at first seem curious, and perhaps even contradictory, given that much of the policy rhetoric emphasises the unique ethical and moral nature of hESC research and how this merits special attention. However, closer examination of the way in which the arguments are set out seem to clear up some of the confusion. In the NBAC report, ethical reasoning used to underpin the argument for federal funding is based on the principles of beneficence and non-maleficence. The former justifies the pursuit of research when the aim is to reduce suffering and the latter justifies the placement of safeguards on the practice of research (Cohen, 2005). It seems that there is significance in using ethical principles grounded in the medical profession for this reasoning.

⁶² It is the same in principle, but the policy literature also includes recommendations for a national oversight panel which would monitor developments in the research. In 2005 it was also suggested that local Embryonic Stem Cell Research Oversight Committees (ESCRO) also be formed as a further oversight level. See discussion in Chapter 2, p. 22-23.

We would argue that such grounding in professional ethics serves to emphasise the nature of scientific research into human embryonic stem cells as a professional discipline in itself. Thus, in a neat parallel to the ideas of scientific autonomy discussed earlier, it seems intended to show that hESC research is something that is governed internally by the professional ethic of scientists. The NBAC's main recommendation that federal funding of research is the best way to both enable and monitor this professional ethic is internally consistent with the ethical reasoning adopted. A similar pattern can be found in the NAS Guidelines. This document has a whole chapter on the ethical issues in stem cell research and the associated implications for governance. This is noteworthy because it is a document specifically aimed at commenting on the scientific practice of hESC research. The fact it goes into such detail in relation to ethical principles of conduct seems to underscore the idea that the scientific profession is both cognisant and capable of upholding ethical principles. Thus, it emerges as a central perspective on good governance.

Though adopting a different framing of the question of federal funding, the arguments in the PCBE report do not negate the above observations about the mutual reinforcement of ethical principles, professional ethics and scientific autonomy. The PCBE re-frames the issue as an 'ethical-political' question about the nature of federal funding, itself.

The decision to fund an activity is more than an offer of resources. It is also a declaration of official national support and endorsement, a positive assertion that the activity in question is deemed by the nation as a whole, through its government, to be good and worthy...[and is] therefore laden with moral and political meaning, well beyond its material importance (PCBE, 2004, p. 37).

By calling attention to the morality of federal funding, the PCBE shifts the focus away from the professional norms of science and towards a question of whether common ground can actually be attained through federal funding if fundamental moral principles are at odds. The question being considered is not necessarily of the same nature, and, therefore, a direct comparison between the three reports cannot be made. We can only conclude by saying that while both the NBAC and NAS reports argue that federal funding is the way to ensure ethical principles are upheld, the PCBE argues the question should first focus on identifying a shared vision of what is being funded. The fact that it is then silent on how federal funding might enforce (or reinforce) ethical principles of research conduct neither supports nor refutes the earlier claims.

However, it does raise the question of how societies should arrive at shared moral values and ethical principles of research conduct. When ethical principles for research are discussed in the UK policy documents, it emerges that national discussion, and broad-based consensus, are important legitimating factors. In the US, these factors seem to vary. This suggests there is an interesting discussion to be had about how such ethically and morally challenging issues are and should be deliberated on within a society so that social and cultural views are respected. These issues will be the topic of section 5.5, but are worth linking to here. For the moment, though, we will complete the discussion under this theme by turning to the moral status of the embryo.

5.4.3 Moral status of the embryo

The moral status of the embryo is, for many, where the debate around the acceptability of hESC research starts. As pointed out by the PCBE, “in the actual public debate, as it has developed, this question seems to have been most central and prominent and probably most responsible for shaping the different basic approaches pursued” (PCBE, 2004, p. 57). These ‘basic approaches’ are arguably shaped by the framing of the embryo within the policy documents. This, in turn, leads to different views on appropriate governance constructs and so helps to shape associated political debates (Kirejczyk, 1999; Parry, 2003). We will find that while in the UK policy documents the embryo is consistently discussed in similar technical terms as the ‘early embryo’ or ‘pre-embryo’, its framing in the US policy literature is less consistent and more ambiguous as to its treatment within a context of good governance.

It is clear in reviewing the policy literature on hESC research in the UK that ‘closure’ around the framing of the embryo in more ‘technical’ terms came through the work of the Warnock Committee in the early 1980s (Warnock, 1985). The Warnock Committee reviewed a range of social, legal, moral, religious, ethical and scientific views related to the status of the embryo and the acceptability of embryo research. These views on the early embryo range from the belief that the embryo is a human being from the moment of conception, to claims that the embryo is just a ball of cells and is therefore no different from any other biological material. Complicating the situation even further is that representations of the embryo are often derived from particular religious principles and so grounded in specific moral systems (see Young, 2001, for a further discussion). As was discussed in Chapter 2, the Warnock Committee adopted a position between the two views – according a ‘special status’ to the embryo –

that was eventually enshrined in legislation and led to the establishment of the ‘14-day rule’. This serves as a shared foundation on which wider governance issues for the science can be discussed, developed and debated.

Though this shared foundation is now the basis of legislation in the area of embryo research, at the time it was delivered, the Warnock Report only went some way towards stabilising the framing of the embryo in a policy setting. A more complete sense of closure within the policy literature came through a shift in rhetoric that was employed over the course of the Parliamentary debates leading up to the passage of the Human Fertilisation and Embryology (HFE) Act of 1990. In his book, *The embryo research debate*, Mulkay (1997) shows how Parliamentarians in favour of passing the HFE Act succeeded in shifting the frame of the debate by repeatedly referring to the developing embryo as the ‘pre-embryo’. By adopting a more scientific term, the embryo could be “treated as un-problematically devoid of human traits, and hence as a suitable object of research” (Jasanoff, 2005, p. 278). Thus, by closing down the terminology, Parliamentarians in favour of embryo research opened up a way for the debate to focus on the issues we have been analysing above: how to respect the ‘special status’ while still allowing for the potential medical benefits for society to be realised.

Evidence of the permanence of this rhetorical shift is found in the fact that in all three of the more recent policy documents being reviewed here, the embryo is consistently referred to as the ‘early embryo’. The ‘early embryo’ is defined as covering “stages of development up to the appearance of the primitive streak”⁶³ (House of Lords Select Committee, 2002, p. 20). This definition is a rather ‘technical’ framing of the embryo, akin to that of the ‘pre-embryo’, which may enable policy discussions to move beyond the issue of the embryo to other governance issues, whilst being safe in the knowledge that the ‘special status’ is enshrined in legislation.

In marked contrast, the varied framings of the embryo in the US policy literature demonstrate how the debate has never reached such closure. This is readily observed in the various presentations of the embryo within the policy literature. In the PCBE report, the first chapter comments on how terminology is used variously in the debate, which can often lead to confusion or a misrepresentation of the issues. They point to the terms ‘embryo’, ‘spare embryo’ and ‘moral status of the embryo’ to illustrate this point. Looking, then, in more detail at the way in which the embryo is referred to in each

⁶³ See discussion in Chapter 2, p. 12, for a definition of the primitive streak and its significance in embryonic development.

document in the context of developing ES cell lines, we first see that in the PCBE report they are described as originating from “the inner cell mass of embryos at the blastocyst stage” (PCBE, 2004, p. 8). The description uses both scientific (blastocyst) and more mainstream (embryo) terms, thus doing little to clarify any ‘confusion’ it points out.

The NAS Guidelines do not use the term ‘embryo’ at all in the description of the derivation of ES cells. Similarly, the NBAC report prefaces the description of how ES cells are derived with the sentence “In mammalian embryonic development, cell division gives rise to differentiated daughter cells that eventually comprise the mature animal” (NBAC, 1999, p. 9). This, combined with the use of the term “early cleavage-stage embryo” seems to reflect a more technical framing of the embryo akin to that in the UK policy literature. Not only does the reference to ‘mammalian’ seem to position the embryo as far as possible from ‘human’, but ‘early cleavage-stage’ is a rather technical description of the stage of embryonic development at which ES cells are derived. One could interpret this as seeking to position ES cells as more suitable for use in scientific research. Other interpretations also exist and we present these here not with the purpose of claiming analytical robustness, but merely to point out that we find three different presentations of the embryo within the US policy literature.

This variation makes discussion of the governance framework and the related perspectives on ‘good’ governance harder to identify as there is no foundational agreement on which the socio-political discussions can rest. In and of itself, this is not necessarily a problem and, indeed, disagreement over social and policy goals is part of the democratic process. However, it does raise questions when we consider it alongside the policy development in each country. One could argue that the relative stability of the status of the embryo has contributed to a clearer presentation of a governance approach in the UK policy literature. A more technical framing of the embryo in the UK policy literature allows for a perspective on good governance which readily seeks a balance between the dual needs to facilitate the science, on the one hand, and uphold the respect for the ‘special status’ of the ‘early embryo’, on the other. In the US, the framing of the embryo varies and is less consistent between the policy documents. This, it seems, results in a mix of perspectives on good governance. Without a consistent framing of the embryo, it is difficult to determine what is deemed to be acceptable treatment of the embryo within a policy and legal context, let alone a research one. The implications of the inconsistent treatment of the embryo, then, as well as the primary framing of

governance issues in ethical and moral terms, may extend far beyond this theme of good governance.

5.5 Establishes appropriate institutions and instruments of governance

5.5.1 Overview

This section will review the different ways in which governance institutions and instruments – such as mechanisms, structures and features of the governance process – are discussed and how different perspectives on good governance emerge from the policy literatures. Section 5.5.2 will focus on the differences in the policy frameworks and policy instruments that are argued for in each set of national policy literature. In the UK, policy instruments are seen as ways to implement regulatory activities, whereas in the US the argument is made for policy institutions that subtly affect oversight through the distribution of research funding. In Section 5.5.3, the quality of the governance deliberations as presented in each set of policy documents will be discussed. Particular attention is paid to how these qualities reflect perspectives on good governance. These topics are discussed in significant breadth and depth in the wider academic literature on hESC research governance, and it is almost impossible to discuss the perspectives on good governance emerging from the UK and US policy documents in isolation from these other literatures. Thus, to a greater degree than in the previous sections, the following discussions will draw on academic and theoretical insights on good governance of hESC research where necessary for purposes of comparison, explanation and theory-building.

5.5.2 Characterising policy approaches

This section will discuss the differences in the UK and US policy documents in terms of the arguments made for policy frameworks that either involve institutions for oversight and funding (in the US) or instruments of regulation for research activities (in the UK). The emphasis on institutions or instruments is relative as both policy frameworks incorporate elements of each. However, it is the case that the UK policy discussion places greater emphasis on specific regulatory approaches to hESC research, while in the US the role of institutions in funding and overseeing ‘appropriate’ research is emphasised. These distinctions, effectively in national governance strategies, are also

observed by others studying patterns in the science and technology policy arena from an interdisciplinary perspective and across many areas of regulatory science (Vogel, 1986; Jasanoff, 2005; Fukuyama and Furger, 2007; Gottweis et al., 2009). In particular, they claim that important differences do exist in areas where government must control the social behaviour of industries heavily reliant upon science (Vogel, 1986).

In further support of this argument, I will claim that in relation to the governance of hESC research, these differences are reflected in a greater focus in the three UK policy documents on the regulatory *processes* of governance, and how it is that these processes come to characterise good governance. In this, we see attention paid to describing the ways in which actors are able to interact and provide inputs to regulatory decisions, the manner in which instruments and institutions operate in their regulatory capacities, and the means through which regulatory oversight is achieved. In the US, on the other hand, we find a focus on the research *outcomes* of institutional oversight strategies and how these outcomes amount to good governance being realised. These outcomes might include the types of research permitted, the principles of scientific autonomy or ethical conduct that are upheld, the ways in which both of these outcomes will shape the scientific trajectory, and, importantly, the types of institutions that best enable all of these ends to be met. Each of these claims will be explored in greater detail below, with particular attention paid to the types of ends that the institutions and instruments of good governance reinforce, such as public confidence, responsiveness, and scientific advance.

In the UK there are three ‘effective’ levels of oversight for hESC research: 1) license application and approval by the HFEA; 2) approval by a local Research Ethics Committee; and 3) receipt of funding by a research council or other funding body. In order to proceed with a research project, then, the researcher must receive approval at all three levels. The first two of these requirements are assured through formal regulatory mechanisms. The UK Government takes pride in the formality of these procedures, arguing that the regulatory controls themselves serve to “promote public confidence in the development and use of human reproductive technologies” (DoH, 2006, p. 5). The House of Lords Select Committee goes so far as to claim that the HFEA has been the “lynchpin” of the regulatory system and

it has the full confidence of the scientific and medical research community, and we believe that it has also been instrumental in reassuring the public that regulation in a particularly emotive area of public policy is carried out effectively and sensitively (House of Lords Select Committee, 2002, p. 38).

Here the regulatory activities themselves and the idea that good governance should promote confidence in all sectors of society are strongly linked. Thus, it is the use of regulatory controls and the way that they are employed which further demonstrates how features of the governance *process* are identified as characteristic of good governance.

In addition to the notion of public confidence emerging out of the process of regulatory oversight, there is also evidence to suggest a belief that the best and most effective regulations will be those that help to advance science and technology. It is argued the regulatory structures must remain “responsive to technological advances”, apace with “significant changes in public attitudes”, and “sufficiently flexible to remain effective” (DoH, 2006, p. 6). These reflect firstly the means (e.g. responsive regulations) and then the ends (e.g. desired scientific outcomes or positive public attitudes), or the process before the outcomes, of good governance.

In the US policy literature, good governance is described more in terms of the outcomes various policies for oversight and funding help to achieve. Here, emphasis is placed on the role of institutions in carrying out indirect roles of oversight through the dispersion of federal funds for research. This mode of oversight, administered primarily through the institutional framework of the NIH and individual research centres around the country, enables particular, and desirable research *outcomes* to be achieved. In arguing in support of oversight through federal funding, the NBAC notes:

one of the principal benefits of federal funding of biomedical and behavioural research is that it is relatively easy to put in place an effective system of public oversight and review...It is a policy strategy designed to provide the appropriate checks and balances and ensure ethically acceptable research protocols (NBAC, 1999, p. 61).

The approach not only favours existing systems, but also a lighter touch that is ‘easy’ to put in place and amounts to a ‘policy strategy’, not formal regulatory activities. In this, we note there are no recommendations that would force compliance in the private sector, indicating a more ‘hands-off’ approach to the process of governance. Privately funded researchers and their sponsors are only “encouraged” to “adopt voluntarily the applicable recommendations of this report” (NBAC, 1999, p. 79).

The NAS Guidelines make recommendations for oversight along similar lines to the NBAC, but with the caveat that further strength be given to institutional oversight at the local level as a complementary layer of review. According to the authors of the guidelines, this would serve to underscore the sensitive nature of the research and foster consistency across the country. Consistency, in turn, would presumably lead to faster

advances in the science. This is particularly relevant due to the timing of the NAS Guidelines' publication, when many initiatives for state-based support and oversight of hESC research were emerging. In both reports, then, we find that desirable policy outcomes are discussed in relation to the relative merits of a system that is already in place. In all of these, the outcomes of good governance seem to be of primary importance.

The analysis so far has been interesting for purposes of identifying perspectives on good governance, but it still seems to beg the question of what the implications are for policy-making and contributions to wider literature. We can return to the tentative suggestion made earlier that where similar comparative observations in national policy styles have been made, notably in the case of Vogel's study of environmental regulation in the UK and US, further support can be found for the assertions being made here. That is, though Vogel's study was focussing on the environmental industry, we would argue that parallels can be seen in the case of hESC research.

Both Great Britain and the United States may be early industrializers, but they have come to pursue markedly divergent strategies for controlling the social behaviour of their industries (Vogel, 1986, p. 266).

Vogel argues that Britain's regulatory style is one where goals remain incremental and there is widespread use of non-governmental organisations to implement regulatory policies and close consultation with industry interest groups before and during the development of new policies. In the US, by contrast, Vogel characterises the American system of regulation as one that has become increasingly pluralist "not only with respect to government regulation but in a wide variety of policy areas" (Vogel, 1985, p. 278). He asserts that the US relationship with industry is one that is marked by persistent strain and "open, unstructured competition among interest groups" (Ibid, p. 279).

Examples of both characterisations are seen in the case of hESC research and within the policy literature being reviewed here. However, for reasons that will become clearer after the presentation of the empirical findings, it is more appropriate to consider both those findings and the conclusions being drawn in the final chapter. The next section will look at perspectives on the qualities of deliberative inputs to good governance.

5.5.3 Qualities of deliberations: the role of publics and the nature of expertise

In the context of this thesis, the term ‘deliberation’ refers to the ways in which discussions and decisions are made in a governance system. The qualities of these deliberations, the nature of the inputs and interactions that take place within them, and the various roles of those engaged in deliberative activities are considered below. In the UK policy documents, we will show that the qualities of deliberations characterising good governance include eliciting the views of the public (usually through some form of consultation activity); having lay representation on expert advisory bodies; placing a value on informed scientific and medical expertise as an input to governance; and ensuring wider expert inputs that are seen to be more ‘social’ in nature, such as those provided through bioethics-based deliberations. In the US, the value of public input is also recognised, but the format through which this should be mediated is less clear. Though there is a value placed upon the role of expert advisory committees, both at the national and institutional levels, it is often through these structures that public input is sought or engagement is mediated⁶⁴. Each area will be discussed in further detail below, under the sub-headings ‘the role of publics’ and ‘expertise’.

The role of publics

A full discussion of the theoretical arguments for why public engagement and deliberation are important in contexts of technological risk and uncertainty is provided in Chapter 3. One of the main points to take away from that nuanced debate and bring into the discussion here is the argument that because this is an area where risks extend beyond the technological and into the social and cultural, the representation of views needs to be broader than individuals from particular “epistemic communities” on expert panels (Fukuyama, 2005). That is, engagement efforts must attempt to represent the entire ‘body politic’ and their diverse views. However, this is not always a straightforward matter and, as Stirling has argued, even the act of designing public engagement and appraisal processes can be subject to different imperatives and motivations, which may serve to close down policy discussions before they begin (Stirling, 2008).

Given the considerable attention paid to this topic in the academic literature, it is curious that there is comparatively little attention paid to the critical examination of the

⁶⁴ We note that in the US public engagement opportunities also exist in the form of voting on public referenda on the issue of stem cell research, but this is not necessarily reflected as a notion of good governance in the policy literature.

issue of public engagement within the policy literature being analysed here. Though there are discussions in the HRT report about the problems associated with the expert-based nature of the composition of the HFEA and the duty of the regulator to ensure public engagement, it is only in later discussion of the new legislation for embryology and fertilisation in the UK that discussion explicitly focuses on the ways in which full public representation might be assured. Even this seems lacking in critical reflection as it only points out that “responses to public consultations often come from those with strong views which may not be representative of those held by the general public” (Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, p. 14).

The situation is made all the more curious by the fact that in the 2005 Human Reproductive Technologies report it adopted what it claimed to be a “significant innovation in the use of e-consultation” where the main aim “was to listen to and gauge the public’s views, both to help us frame the inquiry’s terms of reference and to allow new voices to contribute to the debate” (House of Commons Science and Technology Select Committee, 2005, p. 4). However, the findings of this consultation are not summarized in a single place in the text of the final report, only in a separate summary report listed on the e-consultation’s forum website. Though various quotations and examples are used throughout the text, showing (at least) some responses were a source of evidence, this does little to demonstrate *how* the responses were evaluated and whether they made a real difference to the findings of the inquiry. This seems puzzling, given the comment made to the House of Commons Science and Technology Select Committee by the (then) Chair of the HFEA, Suzi Leather.

The HFEA must respect and *be seen to take on board* the concerns of individuals and groups who invest huge amounts of time and resources in contributing to the debate, and yet often feel marginalized and excluded from the decision-making process (emphasis added, House of Commons Science and Technology Select Committee, 2005, p. 155).

This statement makes it clear that the regulatory authorities recognize the importance of the public’s opinion, yet the comment ‘be seen to take on board’ is particularly ambiguous as to how it will be taken on board, and, moreover, how the public will be able to know their views have actually been taken on board. In the absence of any critical reflection on how one might know whether the aims of a consultation were achieved, and perhaps more fundamentally, articulating what these aims might be, any broad brush statements about the importance of consultation, though welcome, unfortunately come across as rather vacuous.

In the US policy documents, there is slightly more critical reflection on the purposes and meaning of public engagement in a broader context, but on closer examination it is also difficult to determine any specific information about what types of public engagement constitute good governance. As mentioned earlier, the NBAC report devotes several pages to the different ways in which morally contentious issues might be deliberated upon within a society and how public policy should, to the greatest extent possible, focus on “ethical values that might be broadly shared” (NBAC, 1999, p. 51). This wider, consensus-based approach to their deliberations is grounded in writings and theories relating to Rawlsian ‘public reason’ (Cohen, 2005), where reason emerges through the articulation of shared fundamental interests and collective political will.

Laudable though this may be to some readers, the NBAC does not recommend specific engagement initiatives that might be undertaken in order to determine what these shared interests might be. Rather, they simply argue that such an approach should form the foundational principle of their own deliberations and recommendations.

Our aim throughout these deliberations has been to formulate a set of recommendations that fully reflects widely shared views that, in our view, would serve the best interests of society (NBAC, 1999, p. 67).

This seems to reflect a position that quality deliberations are not about facilitating broad-based public dialogue, but rather are about gathering ‘public views’ specifically for the purpose of informing expert advisory panels. The dissatisfaction with this lies in the lack of clarity about how the public’s views are first gathered, and second considered by such panels.

The NAS Guidelines and PCBE report make reference to deliberative principles, but again neither offer tangible ideas about the role that public engagement might play. In its recommendation about the formation of a national oversight body to monitor developments in hESC research, the NAS Guidelines simply advise that such a body must also “pay careful attention to evidence and argumentation in its deliberations, as well as taking into account the diverse views of the public on these sensitive and evolving issues” (NRC and IOM, 2005, p. 59). The PCBE report is even more ambiguous as to what might be needed in the way of public engagement. It points out that it is important to discuss the ways in which society deliberates on profoundly contentious matters and that the hESC research debate provides a “valuable opportunity to think through the ways in which the American policy debates” such issues (PCBE, 2004, p. 94). However, the discussion ends without giving any resolution to the dilemma or suggestions for improvement. As Cohen points out, for a body whose

empowering charter directed them “to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioural science and technology” (Bush, 2001), it seems strange that they do not offer any plausible suggestions about how society might structure its discussions about these issues, debate ways forward or indeed participate more fully in the democratic process (Cohen, 2005).

Thus, although each national body of policy literature acknowledges the idea that good governance will involve making efforts to engage the public and ensure representativeness, little in the way of critical reflection on what meaningful public engagement should seek to achieve or be characterised by is presented. This seems remarkably unsatisfactory given the heightened attention paid to public engagement discussions and characterisations of its importance in terms of good governance in the wider academic literature on new biotechnologies.

Expertise and bioethics

While public inputs are viewed as important, albeit ill-defined and poorly reflected on, the role of expertise is widely discussed in much of the policy literature and, as we will find, has an interesting relationship with the role of the public in the context of hESC research. Though academic work discussed in the previous chapter has shown expertise and singularly technocratic approaches to governance to be flawed, we cannot deny the fact that when it comes to scientific policy issues, some expert input will be required. A tension manifests itself, then, when governments argue on the one hand that “ultimate authority on issues of public concern should lie outside of the scientific and medical communities”, while in the same breath reminding us that, nevertheless, “it is important that any decisions are informed by science and medicine” (House of Commons Science and Technology Select Committee, 2005, p. 182). It seems that the appropriate role for scientific inputs to decision-making differs depending on one’s point of view.

In her book *Designs on Nature*, Jasanoff (2005) reminds us that the public often turns to experts when issues of risk and uncertainty arise. This gives experts a heightened importance in the decision-making process, and, thus, in the wider governance picture. “In the politics of biotechnology, as on any issue of public moment, the credibility of experts is therefore as crucial to democratic governance as is the legitimacy of officials” (Jasanoff, 2005, p. 267). However, the way in which this credibility is established and subsequently conferred within different countries is less

certain. Jasanoff argues these features vary between cultures and are related to the different processes of knowledge generation in a society. She characterises such processes as a nation's 'civic epistemology' (Jasanoff, 2005).⁶⁵ Such epistemologies have different dimensions which contribute to their characterisation, one of which is the way 'expertise' is collectively recognised within a society. Thus, in relation to experts, she claims that variations can be found in the balance between an expert's formal qualifications on the one hand and their personal or institutional experiences, on the other (Jasanoff, 2005). In the US, professional skills and standing in one's field are given much more weight than one's experiences. Skills and standing are seen to be more measurable qualities, and, thus, easier to quantify and prove. In the UK, on the other hand, personal experiences and institutional service are more important (*ibid.*).

In the UK policy documents, the principle of lay representation on expert advisory bodies seems to be of fundamental importance. The main regulatory body for hESC research, the HFEA, is required by law to have a lay majority. This principle was argued by the Warnock Committee, as it believed an advisory body for embryo and fertility research should "not exclusively, or even primarily, [be] a medical or scientific body. It is concerned essentially with broader matters and the protection of the public interest" (Warnock, 1985, p. 76). Therefore, those lay members of the body would be appointed because of their services to society in other areas and not for their professional skills or technical background in the area of human reproduction or science. A clear perspective on good governance emerges where the principle of lay representation becomes a part of the nature of expertise.

In the US, similar calls have been made for members of the public to sit on stem cell oversight committees, but there is little or no guidance given as to how these members should be chosen. Though this is also the case in the UK, at least broad suggestions about composition are made in the legislative statute for hESC research, whereas in the US policy documents it seems there is only lip service to the notion. The NAS Guidelines call for membership of the national oversight body to be comprised of "nationally and internationally recognised authorities in the scientific, medical, ethical and legal issues, and representatives of the public" (NAS, 2005, p. 59). The NBAC states that its recommended national oversight panel should have "a broad, multidisciplinary membership, including members of the general public" (NBAC, 1999, p. 76). Thus, though it is clear that respected experts in various professional fields

⁶⁵ Each epistemology is discussed in full in Chapter 8.

should be represented, it is less clear precisely how and in what proportions the members of the public should be represented on these bodies or the rationale behind their inclusion. If we are to accept Jasanoff's claim as to cultural differences in how experts are defined, we might expect members of the public with significant professional skills and standing to be selected. However, though the NAS report makes some reference to 'recognised authorities', there is little other evidence of selection criteria in the policy documents to verify this claim. We are still left with a question mark as to the exact perspective on good governance in this area and what, if any, relationship to the role of the public in deliberative activities exists.

Part of the answer might lie in the emergence of a new type of expertise that is coming to dominate the types of expert input seen as necessary by policy-makers: bioethical expertise. It is argued that the 'politics of biotechnology' has given rise to this unique type of expert body, which serves as a deliberative mechanism able to consider a host of values and moral issues at stake. 'Bioethics' has thus arisen as the language of choice for many expert-based discussions, at both the national and international level (Gottweis et al., 2009) and on a variety of different biotechnology issues. These range from GM crops, where it has been used to set a risk/ethics boundary (Wynne, 2001; Levidow and Carr, 1997); to xenotransplantation, where it might serve as a language of authenticity (Brown and Michael, 2002); to genetic technologies, where advances in research are seen to force a deeper "political examination of personal and social values" (Knoppers and Chadwick, 2005, p. 75; see also, Salter and Jones, 2002; Kerr, 2003) and, of course, to hESC research, where the focus is on the moral status of the embryo and on wider issues of ethical conduct of the research (Robertson, 1999; European Group on Ethics, 2000; NBAC, 1999; Nuffield Council on Bioethics, 2000; Kelly, 2003; Walters, 2004; PCBE, 2004; Salter and Salter, 2007). Due to the value of bioethics in different contexts, particularly national contexts, it has been argued that bioethics is a new type of "global moral currency" that governments and publics can trade in (Salter and Salter, 2007; Gottweis et al., 2009).

The question then becomes one of how this new arena of expertise has been used in UK and US policy documents to deliberate on the topic of hESC research. Jasanoff argues that in the US the language of bioethics was used to head off the growing fears of the risks posed by new developments in biomedicine, while in Britain it was seen as a way to protect science and the research community (Jasanoff, 2005, p. 187). As much of the analysis in this chapter has shown, in both the UK and the US, policy discussions

over hESC research have taken place with extensive reference to and framing within the moral and ethical language of bioethics. More importantly, the nature of these discussions has varied between national bodies. Thus, the relative impact of the framing of the governance issues within a moral and ethical context seems to have an effect on the perspectives on good governance emerging from the policy literature. For example, while in the UK the moral status of the embryo was established in 1990 in legislation and the framing of the embryo has remained fairly consistent in the literature since, in the US a process of re-framing seems to occur with each new national bioethics body asked to advise on the issue. In addition, though the UK does not have a single official body solely concerned with the area of bioethics, general deliberations over bioethics feature prominently in policy debates, whether mediated through specialist ‘official’ committees (e.g. the HFEA, the Human Genetics Commission (HGC), the Agricultural and Environmental Biotechnology Commission (AEBC), etc.) or ‘unofficial’ bodies with tacit government approval (e.g. the Nuffield Council on Bioethics).

Thus, as Jasanoff argues in her review, in response to the challenges raised by advances in biotechnology, including hESC research, bioethics offers governments the “promise of bringing order and principle to domains previously governed by irrational, emotive and unanalyzed reactions” (Jasanoff, 2005, p. 172). In much the same way policy-makers looked to technical risk analyses or expert appraisal when confronted with scientific uncertainty, it seems they now look to bioethical expertise as a way to make sense of and in some way legitimise – in social and cultural terms – the use and applications of biotechnology. Indeed, it has been argued that in the absence of meaningful public engagement methods, as discussed above, a moral authority is conferred upon public bioethics bodies due to their location, expertise and composition (Kelly, 2003). It is within public bioethics bodies that concepts such as ‘consensus-building’ (Moreno, 1995) and ‘value pluralism’ merge with deliberative principles from the democratic theory literature (Gutmann and Thompson, 1997, 1996). In this way, bioethics bodies are able to lay claim to both deliberative and representative authority.

However, though the aims of consensus within bioethics are easily articulated, in much the same ways as we saw for public engagement in the policy documents, there is still a looming question as to whether, *in practice*, bioethics bodies come up short. Do they provide a full representation of the views of the public(s) they claim to speak for, or help to identify a consensus (Kelly, 2003)? In this respect, it is worth noting that the vast majority of bioethics bodies deliberating on issues of hESC research (be they

official bodies of nation-states or local Institutional Review Boards (IRBs)), are comprised mainly of medical scientists, lawyers, and laypeople, but not necessarily those trained in philosophy or ethics (Gottweis et al., 2009).

This seems to suggest that although public engagement is believed to have a role in the context of good governance, it is still embedded within a role of expertise as the main deliberative focus for issues of scientific uncertainty. The policy and academic literature analysis above presents bioethics as a way to formally deliberate and articulate matters of public concern, perhaps bridging the ‘expert’ and the ‘public’. However, is this merely a new way of framing expert input? Just as with other bodies of more ‘technical’ expertise, the politicisation of the endeavour cannot be ignored as “bioethics” is just as easily susceptible to taking on elements of a “biopolitics” (Callahan, 2006; Bishop and Jotterand, 2006). Though they may aim to either ‘canvass’ (NBAC, 1999) or probe the moral basis of an ‘ethical-political’ issue (PCBE, 2002), there is a strong argument to be made that ‘bioethics’ cannot be a simple substitution for more broad-based mechanisms of public engagement and deliberation.

5.6 *Social and cultural bases of good governance*

5.6.1 Overview

This section addresses the social and cultural aspects of good governance as raised in the policy literature. It touches on the importance of historical and political legacies in policy development, or the relative desires to maintain the ‘status quo’, and from this, how conceptions of the social and cultural bases of trust emerge. In the latter area, there are clear links between the ‘status quo’ and trust in introducing new governance ideas, but more nuanced references to the basis of trust in the context of good governance.

5.6.2 The status quo

It is nothing new to state that existing regulatory structures and political histories influence the current nature of policy debates and, in the case of this thesis, the various elements of good governance that are contained within the policy documents being analysed here. References to these histories and existing regimes are used in various ways within the literature in order to legitimise certain recommendations, courses of

action, presentations of the technologies or framings of the science. In a particularly insightful bridge between the political science and STS literatures, Banchoff (2005) argues that when it comes to value-driven policy issues, like stem cell research, a path-dependent analysis of policy change and exploration is merited. His argument is similar to that being made here, that is, there is a relative importance of history and culture as they affect perspectives on good governance and shape emerging policy discourse.

Insights such as these help to reinforce the argument that references to existing regulatory or policy authorities serve to complement, strengthen and confer legitimacy upon new notions about good governance. They reflect a desire that, for want of a better phrase, is about maintaining, or appearing to maintain, the status quo. For example, in the UK there has been a “long-standing tradition of promoting scientific freedom” (Knowles, 2004, p. 160) and it can be argued that this frame of reference contributes to the increasingly permissive regulatory regime for hESC research. By showing how current regulatory controls have ensured ethical and responsible science while still allowing for scientific progress to be made, the UK Government has been able to make a case for new degrees of flexibility, transparency or consistency. This was seen in the case of the introduction of new regulations for research introduced in 2001 and the new legislative framework introduced in 2008.⁶⁶

Though the US also has a history of supporting the biomedical enterprise (Resnik, 1999), this is in a more ‘free-market’ way through the provision of research funding. References to the success of this system and a history of self-regulation by scientists in new and advancing areas allow for good governance to be portrayed as something that does not upset the status quo, but still acknowledges public concern. In reviewing the arguments in favour of federal funding for certain types of stem cell research, the NBAC report points to: “the enhancement of scientific progress” (NBAC, 1999, p. 58); the benefits that would emerge from a system that “encourages” both public and private support of the research (*ibid.*, p. 59); the “synergies” that would result from combined federal efforts (*ibid.*, p. 59); the application of federal regulations; and the greater ability of the US to “sustain a leadership position in this increasingly important area of research” (*ibid.*, p. 60). There is clearly a balance being struck between emphasising the positive benefits to science and to society through ensuring appropriate levels of oversight. The NAS Guidelines make an even stronger case for relying on past precedents when arguing that self-regulation is entirely merited:

⁶⁶ Both of these examples have been discussed in detail earlier in this chapter and in Chapter 2.

there is a precedent for self-regulation by the scientific community and research institutions... The initiative taken by the scientific community in the 1970's with regard to recombinant DNA research serves as a model for self-governance in hES cell research in the absence of involvement of the federal government (NRC and IOM, 2005, p. 47).

Both examples from the UK and the US suggest that it is through appeals and references to existing processes of oversight that a certain legitimacy comes to be conferred upon the perspectives on good governance that emerge from the policy literature itself. Due to its grounding in the 'status quo', such a legitimacy seems to have clear links to social and cultural bases. These are explored further in the next section.

5.6.2 Bases of trust

Closely related to the issues discussed above are differences in the social and cultural bases of trust. In her comparative study of different cultural responses to biotechnology and the civic epistemologies they reveal, Jasanoff argues that the bases for trust come from the ways in which public accountability is assured in different countries (Jasanoff, 2005). Accountability is conferred in the US, then, through the judicial litigation process where one is able to establish credibility through the courts. In the UK, Jasanoff argues that accountability is conferred by the experts sitting on advisory bodies or making regulatory decisions. It follows that it is through the judgements of such 'trustworthy' experts that the public deems decisions to be credible, acceptable, and, hence, accountable.

However, the analysis in previous sections of this chapter seems to suggest that there are other bases of trust that are important to recognise. For example, though there is a high degree of import given to the deliberations and (claimed) representativeness of expert bodies in the UK policy literature, there is also great emphasis on the legislative principles that underpin regulatory practice. In addition, the practice of legal challenge is not mentioned in the US policy documents on hESC research, and so here, too, other bases of trust may exist.

One way to think about trust is to ask why trust is sought and by whom. In a review of the governance of human genetics in the UK, Jones argues that

Although trust in a governance system may seem inherently 'good', from a pragmatic policy perspective there are compelling reasons for its nurture—the strongest of which is the state's need for legitimacy... Principally, although trust and legitimacy cannot be equated, trust is a lynchpin of political legitimacy. (Jones, 2004, p. 252).

Thus, though not equal, trust and legitimacy seem linked. Jones goes on to explore the use of objectivity in decision-making activities as a basis for establishing rhetorical legitimacy, and hence, trust. Using Jones' approach, we will look for similar links and evidence of appeals to both legitimacy and trust in the policy literature. It seems to us that references in the policy documents to the 'status quo' in governance processes (as discussed above) and/or support for current and past regulatory practices, are similarly used as 'objective' statements to 'stretch' (Jones, 2004) the arguments into a foundation for establishing trust and legitimacy.

In the 2002 Select Committee Report from the House of Lords, we find that in their description of the current framework within which hESC research is permitted and regulated, they refer three times in the same paragraph to perceived indicators of public support. They find that the "majority public opinion" is supportive of stem cell research, that the regulatory authority for stem cell and embryo research enjoys "public support" and, moreover, was "enacted after a lengthy period of public and parliamentary debate." They go on to point out that the legislation and regulatory authorities have "been in force for ten years", which seems a direct reference to the importance of the status quo (House of Lords Select Committee, 2002, p. 23). It seems, then, that within this policy document a perspective on good governance emerges that emphasises continuation of the status quo precisely because it enjoys strong support, high levels of public confidence and is based upon 'legitimate' processes of previous public debate, which include the morally and ethically-derived conclusions of the Warnock Report.

In the US policy documents, trust seems to be sought in emphasising the state's established precedent in responsible scientific oversight. Since previous areas of science have been overseen through federal funding, the aim seems to be to convince the public that trust can be placed in government to ensure hESC science will be conducted in a responsible way. Further, more nuanced, appeals to legitimacy are found in the way this argument is made through references to the moral import of this activity. Thus, a link is made between the appeals to confidence in the system and the shared moral sensitivities of Americans. The following excerpt from the NBAC report is illustrative of this attempt:

We concluded that sufficient safeguards can be put in place in order to prevent abuse and to ensure that any use of embryos...[this] embodies the kind of respect for the embryos that most Americans would expect and demand of any activity that is carried out with the support of the federal government (NBAC, 1999, p. 67).

The report goes on to further appeal to the sensibilities of Americans in pointing out that “the development of such policy in a morally contested area is not a novel challenge for a pluralistic democracy such as that which exists in the United States” (NBAC, 1999, p. 67). The reader is thus both reminded that these types of issues are not new and their government has successfully dealt with issues of similar moral import before.

To conclude, in the US the basis for trust seems to rest on a reference to established precedent in scientific oversight, which is reinforced by the legitimacy language of morality, ethics and cultural pluralism. In the UK, bases of trust seem to be more closely tied to the framework of regulatory oversight that has proven, over time, to protect the public, allay fears about violation of moral sensitivities, and enable scientists to move forward with the research. The differences between the two countries are thus subtle, yet important, and tie in with the wider perspectives on good governance of hESC research that the analysis in this chapter has sought to uncover.

5.7 Conclusion

In conclusion, this chapter has looked at the systematic patterns in perspectives on good governance that emerge from a sub-set of the national policy literature for hESC research in the US and the UK. These perspectives emerged across four main themes of good governance, concerning the extent to which good governance: 1) Advances scientific and technological outcomes and addresses related issues in hESC research; 2) Encourages moral and ethical awareness for hESC research; 3) Establishes appropriate institutions and instruments of oversight for hESC research and 4) Identifiable social and cultural bases of good governance emerge. Each of these themes were found to be covered to varying extents and in different ways within each of the policy literatures, with no significant additional issues emerging. This underscores the robustness of these four themes as an analytical framework for analysing perspectives on good governance within different national policy contexts.

More specifically, the discussion above under each of the four themes distinguishes systematic patterns in the perspectives on good governance in the US and UK policy literatures. There are similarities in the ways both sets of policy literatures use moral and ethical language to characterise, describe, and in some cases frame, many of the governance issues relevant to hESC research. This is seen both in the central role played by the ethical and moral discussions, but also in the fact that the role of bioethics

has emerged as a dominant, and perhaps legitimacy, input to policy-making in both countries. The full implications of this observation in comparison with the findings of the MCM interviews will be discussed in Chapter 8.

However, differences were found in the way the nature of hESC research was framed in both sets of policy literatures as well as in the characterisations of policy approaches. The UK policy literature has a greater emphasis on the realisation of therapeutic benefits of hESC research as soon as possible, and thus measures are outlined as to how direct government support may help to achieve this. The US policy literature, by contrast, displays a greater emphasis on an indirect governance approach that characterises scientific outcomes in relation to the relative degree of scientific autonomy afforded to researchers. This results in more outcome-based policies which seem to focus less on the processes of governance and more simply on letting science ‘get on with it’. Conversely, the UK policy literature seems to have greater concern with the processes of regulation and oversight as a means through which therapeutic outcomes of the science may be achieved.

We will now turn from the findings of the review of core policy documents and associated literatures, to presentation and discussion of the first set of empirical data. The analysis in the next chapter concerns the national characteristics of perspectives on good governance arising from MCM stakeholder interviews.

6. Perspectives on good governance: comparative analysis of the US and UK

6.1 Introduction

6.1.1 Overview

The analysis presented in previous chapters has shown that human embryonic stem cell (hESC) research presents a classic case of scientific and technological uncertainty where facts differ and conditions are unknown, assumptions varied and stakes are high (Funtowicz and Ravetz, 1993). The reality, though, is that despite these circumstances, policy-makers, industrialists, scientists and publics alike must be able to shape ways forward (of whatever kind), build justifications for and legitimise their decisions, and integrate all of this in a wider governance context.

This thesis is concerned with the question: Are there contrasting perspectives on what constitutes ‘good governance’ for hESC research amongst different groups of stakeholders in the UK and the US and do systematic patterns emerge? Several sub-questions fall from this, including how do such divergent perspectives differ across stakeholder groups and national contexts? Are perspectives affected by individual and collective ideas, assumptions and framings? How might these be empirically elicited? From these questions, the hypotheses for this thesis emerged:

- *It is possible to discern discrete perspectives on good governance and systematic differences in these between and within groups of stakeholders in the UK and the US.*
- *Among these perspectives, patterns and regularities can be identified and analysed between and within the national and cultural settings.*
- *Methods of empirical analysis can allow us to understand how the perspectives on good governance are constructed and the patterns that emerge from their comparisons.*
- *Distinctions between and patterns within perspectives on good governance from stakeholders can be compared with the formal policy literature in each country and discernible distinctions can be analysed.*

This chapter and the next will address these hypotheses and discuss the analytical findings arising from the MCM interviews. Selecting among the many possible dimensions for analysis was one of the initial challenges for the research, as was

discussed in the methodology chapter.⁶⁷ The remainder of this chapter will focus on discerning the differences between UK and US participants, while the following chapter will analyse the differences between multiple perspectives at the level of different groupings of policy actors across the two national settings. Throughout the discussion, we use the term ‘perspective’ to refer to discernible distinctions and regularities that emerge in the analysis of these different stakeholder groups, rather than to imply reified discrete phenomena in the empirical fields themselves. Approaching the analysis in this way allows for a targeted approach to addressing the main hypotheses of this thesis, as well as a focused analysis of each of the main areas of exploration—that is, cross-country differences in perspectives on good governance, as well as cross-stakeholder differences within specific national contexts.

The next sub-section will discuss implications arising from the high-level analysis of the empirical findings of UK and US perspectives on good governance. We will then ‘preview’ the main patterns in divergent perspectives which emerge from the analysis presented in this chapter. Sections 6.2 and 6.3 will present the findings in full under two of the themes of good governance described in the previous chapter.⁶⁸ A few points about the presentation and discussion of the findings are worth making before we begin. First, an MCM empirical analysis of stakeholder perspectives is informed both by attention to rankings, as well as more fine-grain framings that are evident in the defining of criteria and the detailed assessments of options. Thus, throughout this chapter and the next, the quantitative picture is supplemented with qualitative material in the form of stakeholder statements from the MCM interviews. Second, given previous comments about the depth and breadth of data, the analysis presented in some themes will be more detailed than others. This is to emphasise those areas where the conclusions were most robust in relation to the hypotheses under examination. Where data is not presented in full, the reader is referred to relevant Annexes as noted in the text.

6.1.2 Analysing final performance rankings

As set out in the methodology chapter,⁶⁹ MCM is a heuristic tool that can be used to explore relationships between technological and socio-political factors in

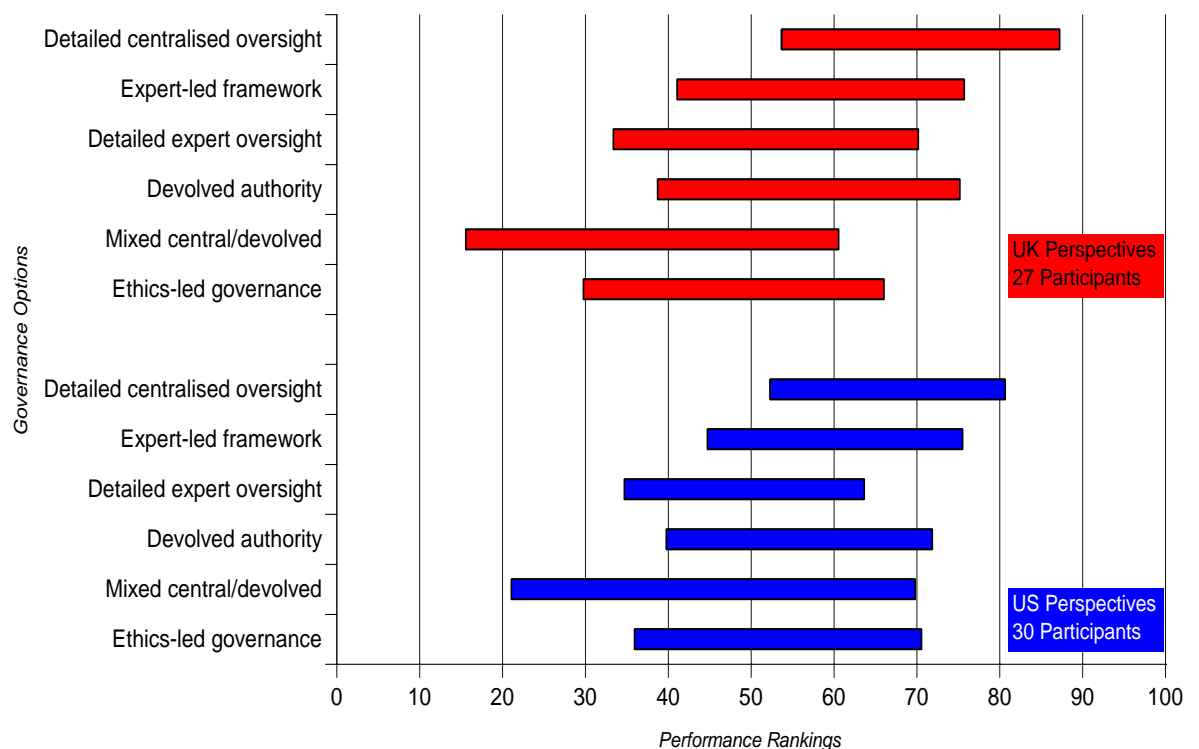
⁶⁷ For example, many different permutations and classifications of both participants and their responses were made and analysed before the dimensions as presented here were settled upon. See the discussions in Chapter 4 for more detail on this point.

⁶⁸ The other two themes of good governance are discussed more fully in Chapter 8.

⁶⁹ See the discussion in Chapter 4, Section 4.2.2 and Section 4.5.

perspectives on good governance and decision-making. In the present analysis, option rankings will be the first point of reference for identifying potential analytical insights, followed by textual and qualitative analysis as discussed above. Figure 6.1 below presents the option performance rankings for UK and US-based stakeholder perspectives. The further the ranking ranges extend to the right, the higher the option performance. The horizontal scale in this (and all subsequent ranking charts) is normalised, such that a value of 100 indicates an option that scores consistently highest in every interview under all possible criteria, whilst a value of 0 indicates an option that scores consistently lowest in every interview under all possible criteria. As explained in the Methodology Chapter, the extreme lower and upper ends of the ranking ranges for each option, are (in this ranking chart as all others in this thesis, except where noted) represented as the *means* respectively of the pessimistic (minimum) and optimistic (maximum) rankings obtained in each case.

Figure 6.1: Rankings under UK and US stakeholder perspectives



An immediate general finding that is consistent with usage of MCM in other exercises where there exist highly divergent framings (see, for example, Stirling and Mayer, 2001; Davies et al., 2003; Millstone et al., 2006), is that no single good governance option ranks as unequivocally best or worst across all these perspectives. The scale of the overlapping ranges for individual options typically far exceeds the

incremental differences between the options themselves. Beyond this ambiguity, however, there is a notable similarity in the ordinal patterns (i.e.,: the relative orderings of options). In particular: *i*) the relationship is consistent across both UK and US perspectives among the first four options (from the top of the y-axis in the charts); and *ii*) there is a relatively wide range of uncertainty and ambiguity evident in the mixed central/devolved option. This degree of congruence is particularly striking given the number of interviewees, the complexity of the options, the uniqueness of the criteria defined by each individual, the open-endedness of the possible framings each individual might adopt, and the degree of latitude each participant has in determining the final outcome of their respective interviews. Against this background, it might be expected that the pictures derived in this analysis would display multiple forms of divergence. Yet it is clear that there exists – at least at this level of analysis – a fairly consistent pattern in the perceived overall performance of the different governance options across the contrasting contexts of the US and UK. Moreover, subject to the caveats set out at the end of Chapter 4,⁷⁰ the degree of consistency in the observed regularities suggest that they are not due to volatilities intrinsic to the method.

It is tempting to conclude that these similarities imply that perspectives on good governance of hESC research across UK and US perspectives are more notable for their similarities than their differences. However, the analysis in the remainder of this chapter will argue that the ways in which perspectives on good governance emerge from these different settings do vary in several potentially significant ways. Though the aggregate pictures – as indicated by the ranking patterns – seem similar, there are deeper complexities, differences between perspectives, and variations in framings that are otherwise masked at the level of overall rankings.

The basic similarities in option performance orderings across US and UK stakeholder perspectives are all the more intriguing when considered in light of some of the comparative literatures that aim to explain generic national differences in policy discourses through the identification of specific cultural, institutional and epistemic differences across nation-states (see for example, Jasanoff, 2005). While national comparisons are necessary and useful at a meta-level of analysis, my findings seem to suggest that these types of comparisons cannot always be assumed sufficient. In other words, despite the fact that the findings presented here reveal contrasts across national settings, there are nonetheless discernible differences between perspectives in each case

⁷⁰ See the discussion in Section 4.5.4, p. 87-89.

that suggest that the picture is much more complex and nuanced. This prompts a conclusion that broad comparisons and distinctions framed at a cross-national level may obscure underlying commonalities, variabilities and contingencies.

In addition to the similarity in the ordinal rankings, three other distinct patterns emerge. First, there is a more extensive degree of uncertainty and/or ambiguity⁷¹ evident in the mixed central/devolved option in both national contexts. For UK-based stakeholders the range between the pessimistic and optimistic assessment scores for this option is about 46 (on an interval scale across all options, normalised to 0-100 as explained above). For US-based stakeholders the same range is about 49. In both cases this exceeds by some 10 base points (or at least 30%) the average scale of the ranking ranges for other options. This suggests there may be some intrinsic features of this option that make it more susceptible to uncertainty or ambiguity in appraisal, regardless of the stakeholder perspective. Contributing factors accounting for this are discussed in this chapter and the next.

Second, there is slightly more differentiation between the performance orderings for the last three options (devolved authority, mixed central/devolved and ethics-led governance) under UK perspectives than under US perspectives. The optimistic assessments for the three options under US perspectives all display fairly similar ranks (around 70 base points).⁷² With the exception of the mixed central/devolved option, the other two options also have similar pessimistic assessment ranks between 38-40. This is in contrast to the rankings under UK perspectives, which exhibit greater variability in rank orderings across these three options. The one thing all three options have in common is a devolved structure of governance with varying degrees of expert input, public deliberations and regulatory oversight. Analysis in the following sections may reveal that UK perspectives find something in a devolved governance structure which renders it more susceptible to variable ‘performance’.

Finally, in both national contexts, there emerges a similar ordinal relationship between the rankings of the devolved authority and expert-led framework options. These options share certain features in common, such as a centralised legislative oversight and some degree of decentralised research oversight, but other features differ.

⁷¹ The difference between measures of uncertainty and ambiguity is a subtle, yet important one and is discussed in the Methodology chapter on p. 86. In short, uncertainty is a measure of the difference between pessimistic and optimistic scores expressed by individual participants, whereas ambiguity is a measure of the differences between the option evaluations made by participants within a perspective.

⁷² The reader is referred to Annex G for a discussion of the mathematical computations behind such ‘aggregate’ scores and mean performance rankings.

A more detailed analysis will enable us to determine why and how these similarities emerge.

We can see that the rankings and the associated reasons surrounding option performance are nuanced and varied. A more detailed exploration and analysis in light of the socio-political viewpoints, framings and assumptions that may affect option performance may therefore be capable of providing insights into how perspectives on good governance are constituted in each country. Table 6.1 below summarises the main patterns in UK and US perspectives that will emerge from this exploration and analysis over the coming chapter. These are presented within the same analytical framework of the themes of good governance that were identified in Chapter 5. There, the themes were found to be relevant and substantially represented in both sets of policy documents. In addition, the analysis revealed differences in framing within the documents and across the themes which were linked to a variety of perspectives on good governance. As one of the hypotheses of this thesis is that the stakeholder perspectives on good governance identified through the empirical analysis may differ from those identified in a formal policymaking context,⁷³ it makes sense to employ the themes of good governance adopted in Chapter 5 to the interview-based findings. Moreover, in applying these themes to the MCM empirical data, we are able to further test the robustness of the themes as an analytical framework and ensure a consistent, systematic and structured probing of the material collected during the course of 57 MCM interviews.

The presentation of Table 6.1 below provides a preview of the findings that will be presented over the rest of this chapter. It is intended to give the reader a sense of the analysis to come and to help guide them through it. Each theme is presented along the horizontal axis and the areas of comparison are summarised along the three vertical columns. Broad summaries of the findings, and corresponding shadings, are given for each comparative area. These findings rest on the relative patterns of prominence in each case as determined by the respective comparative axis. For example, the analysis of the policy document-based perspectives in the previous chapter provides the grounds for comparison along that axis. The basis for the MCM-based stakeholder perspectives will be discussed in detail in this chapter. These were arrived at through the methodological process described in detail in Chapter 4. First, criteria are allocated to

⁷³ A 'formal policymaking context' is here taken to mean those expressed in the 'core policy documents' selected and analysed in Chapter 5.

themes on the basis of their definitions and, second, the associated assessments, weightings, rankings and other relevant qualitative and quantitative data-points (such as uncertainty and ambiguity) are explored. The analysis continues in an iterative fashion until the analyst is satisfied that all alternative explanations have been accounted for and a prominent perspective is identified.

Table 6.1. Summary table of patterns in perspectives across all themes of good governance

		Perspectives from US Policy literature vs. US stakeholders	Perspectives from UK Policy literature vs. UK stakeholders	Perspectives of US stakeholders vs. UK stakeholders
Advancing scientific & technological issues in hESC research	Quality of scientific outcomes	Slight divergence	Slight divergence	Slight divergence
	Research support	Broadly congruent	Broadly congruent	Noticeably divergent
Encourages ethical & moral awareness for hESC research	Principles of research conduct	Discussed in Chapter 8		
	Moral status of the embryo	Discussed in Chapter 8		
Establishes appropriate institutions & instruments for hESC research	Characterisations of policy approaches	Discussed in Chapter 8		
	Qualities of deliberative activities: publics	Slight divergence	Slight divergence ⁷⁴	Slight divergence
	Qualities of deliberative activities: expertise	Slight convergence	Broadly congruent	Slight divergence
Identifiable social & cultural bases of good governance emerge	Bases of trust and legitimacy	Not analysed in full		
	Maintaining continuity	Not analysed in full		

Shading Key

	<i>Noticeably divergent: Distinct differences across the two perspectives are clear and readily identifiable</i>
	<i>Slightly divergent: Some differences across the two perspectives are clear, but similarities or unclear signals exist.</i>
	<i>Slightly convergent: Some similarities across the two perspectives are clear, but differences or unclear signals</i>
	<i>Broadly congruent: Similar patterns across the two perspectives are clear and readily identifiable.</i>

⁷⁴ See discussion in related section (Section 6.3.2) for caveats.

A few points from the table are worth noting. First, the reader will observe that some of the analysis within a theme is discussed in Chapter 8. This is because the findings were found to cut across both national settings and individual stakeholder perspectives in important and illuminating ways. In addition, though the four main themes remain the same, some of the sub-themes have been merged for the empirical analysis. This is due to the differing nature of the two sets of empirical findings and the fact that a one-to-one correspondence was not always found, nor was it always appropriate. For ease of reference, the reader will note that each ‘theme’-related portion of the table is reproduced at the end of each section in order to summarise the analysis that has preceded it. The table is then reproduced again, in full, at the end of the chapter for the final summary. We will now move to discussing each of these patterns and the empirical evidence to support them in greater detail. We begin with the theme of good governance relating to ‘advancing scientific and technological issues in hESC research’.

6.2 *Advancing scientific and technological outcomes*

6.2.1 Overview

Chapter 5 discussed the patterns that emerged within and between different themes of good governance for a subset of the UK and US policy literature. Within the theme ‘advancing scientific and technological outcomes’, it was argued there were clear differences between UK and US policy documents in the framing of hESC research outcomes and the elements of good governance that would be needed to achieve them. In the US policy literature, there was a prominent view that if a flexible space for the autonomous pursuit of science was created, a host of scientific outcomes could be realised. These outcomes included, but were not limited to, therapeutic ones. Research support, therefore, should serve to harmonise oversight frameworks and policies so that science can progress relatively ‘unfettered’. By contrast, in the UK policy documents ‘good’ outcomes of hESC research were more prominently characterised in a therapeutic way. Processes of research support, then, should involve ‘direct’ government efforts, such as creation of a permissive regulatory space, aimed at more quickly advancing hESC research.

The question now arises of how stakeholders express perspectives on good governance in this area. Given the different nature of the empirical findings from the

policy literature, the analysis here will look simultaneously at the different perspectives on the framing of ‘quality scientific outcomes’ of hESC research and the processes of research support. Discussion of the therapeutic and technological trajectories of hESC research will also be covered within this discussion. The section will conclude by summarising the most prominent patterns within the perspective for this theme.

6.2.2 Scientific outcomes and research support

In the analysis presented in this section, attention will focus on option performance and criteria definition as characterised specifically under the MCM analytical issue ‘advancing the science’. The definition of this as an issue for MCM analysis arises both from consideration of the good governance themes previously introduced, as well as from systematic testing and probing of the empirical material in an open and transparent way.⁷⁵ Thus, the criteria that comprise this issue reveal not only the ways in which qualities of hESC research outcomes are perceived as ‘good’ by stakeholders, but also the ways in which these perceptions reveal particular framings about the nature of the science, the processes of research support that enable these, and the assumptions, judgements and values that affect these framings. With this in mind, the issue used for the analysis is defined in the following way:

***Advancing the science:** Criteria in this issue are distinctive in their concern with fostering and advancing the science of hESC research itself. Often expressed in an instrumental⁷⁶ way, the criteria are concerned with the need for the governance framework to facilitate, support and actively advance the research, technological and therapeutic trajectories of human embryonic stem cell research.*

Criteria falling within this issue were the most frequently mentioned by all participants across all perspectives.⁷⁷ Thus, the following discussion will go into greater depth than later sections due to the detail that is required in order to explore nuances in the framings and perspectives on hESC research that emerge. The chart below shows the rankings under UK and US participant perspectives under the issue ‘advancing the

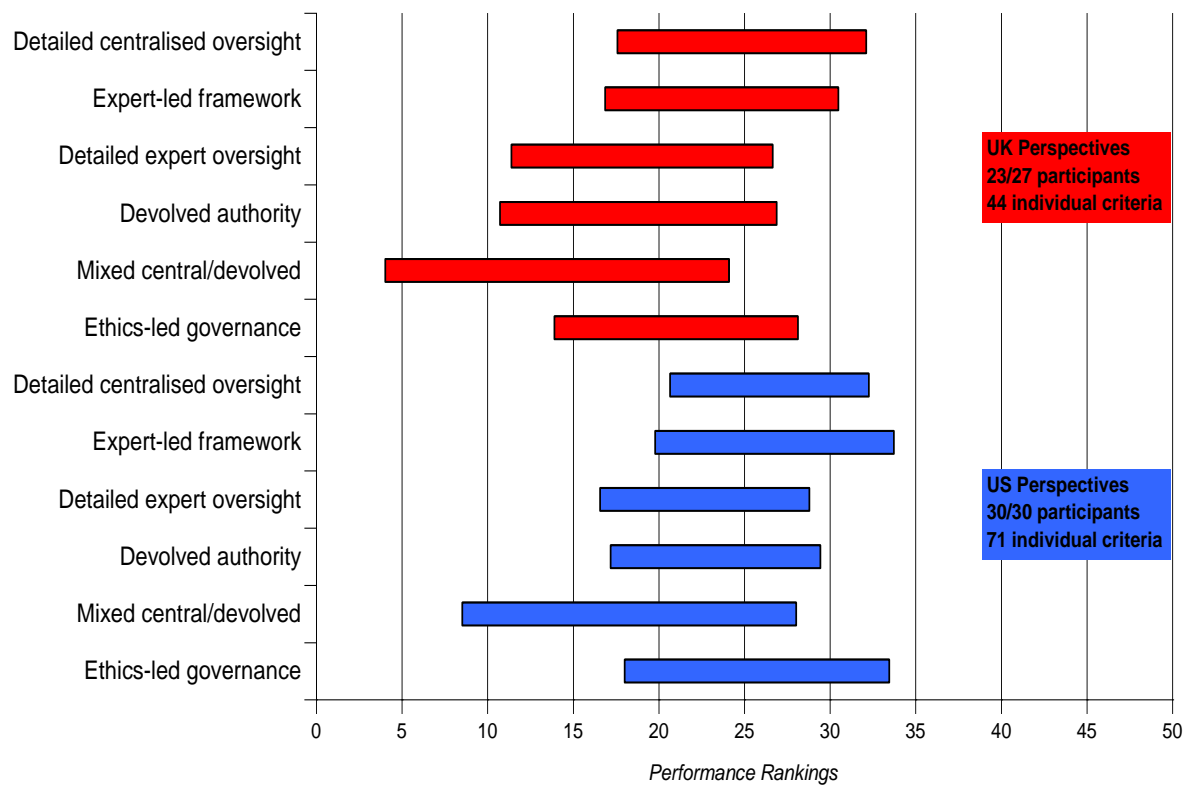
⁷⁵ The reader is referred to discussion earlier in this chapter on p. 135-136, as well as to discussion in Chapter 4, Section 4.5, p 81-87 as to how the analysis of the MCM empirical material was conducted and prominent patterns within the findings identified.

⁷⁶ Throughout this chapter and the next, use of the terms ‘instrumental’, ‘normative’ or ‘substantive’ will be used according to the interpretations discussed earlier in Chapter 3, p. 52-53. A fuller discussion of the implications of the empirical findings for these theoretical concepts is given in Chapter 8 and cuts across both the analysis presented in this chapter and that in the next. In the case of the issue definition above, ‘instrumental’ refers to the fact that the criteria reveal instrumentally motivated concerns about particular research ends, or technological outcomes, being realised and correspondingly supported.

⁷⁷ A full list of criteria defined for the MCM interviews is provided in Annex H.

science’. As has been discussed previously,⁷⁸ the various dimensions of option performance illuminated in MCM provide a heuristic framework that can be used to explore the relationships between technological and socio-political factors that constitute divergent notions of good governance. As part of this, an initial analysis of the patterns that emerge from the rankings above (that is the overall ordinal sequence and associated intervals reflecting uncertainty and ambiguity) can be used to guide the more detailed analysis.

Figure 6.2. Rankings under UK and US perspectives for ‘advancing the science’ criteria⁷⁹



We can see that, on the whole, the option rankings are broadly similar. However, there are potentially significant differences in rankings. These include: *i*) the notably greater uncertainty/ambiguity in the ranking interval for the mixed central/devolved option for US and UK stakeholder groups; *ii*) the higher ranking of the expert-led framework option under US perspectives as compared to the higher ranking of the

⁷⁸ See the discussion in the methodology chapter, Section 4.5, p. 81-87.

⁷⁹ When ranking patterns are presented under criteria groups (issues), only a subset of all criteria may fall within any given grouping. Similarly, not all participants in the stakeholder group (perspective) being analysed may have defined a criterion within the issue, or some participants may have defined several criteria within the issue. Thus, each box in the figure displays information regarding the number of participants defining at least one criterion within the issue (e.g., ‘x/x participants’) and how many criteria, in total, comprise the issue within that perspective (e.g., ‘x individual criteria’).

detailed centralised oversight option under UK perspectives, and, *iii*) correspondingly, the higher performance of both the expert-led framework and ethics-led governance options under US perspectives. On this final point, the fact that the two options are more indirect, or ‘hands-off’, in terms of oversight instruments than the other options may be significant. This seems to suggest that for US perspectives there is a discernible underlying pattern indicating a relative preference for less centralised and less regulated governance options under this issue. If this is the case, we expect to see confirmation of this in the qualitative assessments of the options under the issue, analysed below.

In addition to the broad similarities of the ranking patterns for both UK and US perspectives, the relative distribution of the criteria within the issue is remarkable. There are notably⁸⁰ fewer individual criteria under this issue for UK than US participants: 44 individual criteria for the former as compared with 71 individual criteria for the latter. Moreover, all 30 US participants defined at least one criterion of this type compared with only 23 UK participants who defined at least one criterion in this issue. However, the differences in relative expressions of importance assigned to the criteria are not as great as the numerical differences suggest. UK participants designate an average importance of 32.5%, as compared with 44% for US participants.⁸¹ There is a slight difference, but perhaps not big enough to warrant full confidence in explaining for the numerical difference we observe. An alternative, or corroborating, explanation as to why US participants defined so many more criteria within this issue, is that they are responding, in some way, to the ‘patchwork’ governance framework for hESC research which was in place at the time the interviews were conducted. Such inconsistencies may have led US participants to qualify their views on similar issues, such as advancing the science, with more criteria than UK participants.

Finally, a less significant feature of the ranking patterns seen above is that there are differences from the rankings for each country as a whole (that is, under all issues as shown in Figure 6.1). This point could also be applicable to many of the analyses that will follow throughout this chapter. This underscores the ability of MCM as a method to

⁸⁰ The author is aware of the implications of using the term ‘significant’ in an analytical context and the association with statistical ‘significance’. The term, therefore, may be used throughout the analysis, but with the connotation merely as one of ‘noteworthiness’ (as indicated by the choice of the term ‘notably’ here), but not to imply statistical significance of any type. As discussed in Chapter 4 (p. 87-89), there are questions over whether qualitative/quantitative MCM data in a study such as this one would support the assumptions necessary for statistical analysis.

⁸¹ A full table of weightings for each of the issues presented in this chapter is provided in Annex I.

distinguish among different perspectives and associated evaluations made under different sets of assumptions and contextual factors.

These observations lead us to the following questions which guide the analysis. First, given the broad similarities in the ranking patterns under this issue, are the criteria that comprise the issue also similar, or are there different framings of the nature of hESC research and desired scientific outcomes? Are there different interpretations of option performance between each country and, if so, what does this tell us about differences in framing in option assessment? In other words, if there are differences in the characterisations of criteria, but similarities in option assessments, or vice versa, will this affect our understanding of the constituting of perspectives on good governance? It will be argued below that more noticeable differences are apparent between UK and US stakeholder perspectives concerning criteria and associated option appraisals. The distinctions evident between the stakeholder perspectives and policy literatures in each respective national context are more subtle, but nonetheless potentially significant.

We will begin by looking at the two types of criteria evident within the UK perspectives.⁸² The first is about the qualities of scientific outcomes which stakeholders believe should be sought, and the second is about what processes of research support should be in place, or, in other words, how achievement of the outcomes should be facilitated. Amongst UK participants, there is a tendency to refer to the achievement of particular scientific outcomes in the context of regulatory support. Thus, the two are portrayed as being mutually dependent: without regulation, advances in hESC research may not occur. Though there is some implicit (and in some cases explicit) acknowledgement that regulation can be a negative force on these trajectories, most participants point out that regulatory forces can be of an “encouraging” (UK bioethicist 2, #C192),⁸³ “enabling” (UK professional body 4, #C329) and “balancing” (UK policy-maker 3, #C170) nature. They emphasise the more ‘positive’ characteristics of regulation and not those where regulation is “being restrictive, being the nay-sayer” (UK bioethicist 2, #C192). With ‘balanced’ or ‘proportionate’ (UK regulator 4, #C123,

⁸² Here, and throughout the analysis in the following chapters, the reader is reminded that a full list of all criteria is provided in Annex H. Thus, individual criteria or reference to groupings of criteria under certain issues can be cross-referenced with the relevant criterion ID number in the text and that in the table in Annex H.

⁸³ Throughout the analysis, supporting statements or examples from the MCM interview data will be referenced in this format. The first part indicates the participant code (see Table E.1 in Annex E for a full list of participants and their ‘codes’). The second part of the reference indicates the MCM element the example or quote comes from. ‘C’ indicates a criterion-based example, ‘A’ indicates an assessment-based example and ‘W’ indicates a weighting-based example.

UK policy-maker 2, #C139) regulation, there is also discussion about ‘flexibility’. Here, regulation needs to be “protective enough for safety and responsive enough to take future developments into account” (UK industry executive 3, #C203). The dominant feature of good governance that emerges in terms of processes of research support is about creating a *‘protected, regulated space’* for scientific outcomes to be achieved in.

However, there is a caveat that regulation should not be burdensome or inflexible so that it “stifles the science” (UK policy-maker 2, #C140) or cannot ‘change as the science changes’ (UK scientist 6, #C314). In this, an interesting framing of hESC research emerges where criteria about the quality of scientific outcomes seem embedded within and intimately linked to the regulatory framework.

So the regulatory system has to look at the realities of the possibilities determined by the way the biology works, it has to be grounded in the science, and it has to be able to factor in the risk, or the perception of risk. ... It’s not only about the best way of doing it, but is it an appropriate application of this type of knowledge. (UK patient advocate 5, #C309).

Here, the stress is on the role of the regulatory system in ensuring that only the highest quality science is permitted. In the stress on the best way of doing things, we find a broader framing of the outcomes of science than was seen in the policy literature, where a more therapeutic orientation was seen in the UK. There is also an implicit link to the idea that science is advanced both as a result of regulations, in that they set a high standard for the science, and because of them, in that the regulatory framework itself assures that only the best and most appropriate types of science are being conducted. This latter point is especially important and is made more explicit by others.

It's about having enough regulation, but no more, to keep the public on board, but still allowing science to get on with it (UK bioethicist 4, #C128).

In this quote, we see a linking of ‘pragmatically’ balanced regulation to the advancement of hESC research, but in a way which brings out another key facet of the link between regulation and scientific advance: regulation as a means through which public support for the science is gained. Since public support is seen as important for enabling the pursuit of specific scientific outcomes, part of the role of regulation is to reassure the public that the science is being conducted in a responsible way. This theme will also come up in later sections, but is worth previewing here. It reveals an important tension between regulation to protect the public and regulation to protect the science. Moreover, it reveals a type of instrumental motivation behind the appraisal criteria which is about the purpose of governance in attaining desired outcomes or ends, such as public trust or quality scientific outcomes.

The discussion and analysis presented thus far allows us to conclude that there is a difference to be found in the way that perspectives on ‘advancing the science’ emerge between the UK policy literature and the UK-based participant perspectives. The therapeutic framing in the UK policy literature was strong as compared to the more varied characterisation of scientific outcomes as needing to be both ‘high quality’ and/or therapeutic by UK participants. Moreover, though both the policy literature and the participants discuss the importance of regulation to protect a space for science, there is a clear instrumental link between three seemingly separate elements of good governance — scientific progress, regulatory oversight and public support.

Overall, the more prominent regulatory framing of the science is supported by the performance rankings under the issue for UK perspectives. The most centralised and regulated option, detailed centralised oversight, receives the highest ranking among UK interviewees. This is supported by qualitative assessments asserting that if regulation were proportionate and balanced, this option would do well at advancing the science. However, the lower end of the assessment reflects concern that it could be too heavy handed, thereby stifling scientific creativity. This tension between centralisation with flexibility can also be seen in the relatively high ranking interval for the expert-led framework option under optimistic assessments and the comparatively low ranking interval for the mixed central/devolved option. The former option has a centralised legislative framework, but a more ‘hands-off’ approach to regulation of hESC research. Thus, the pessimistic end of the ranking reflects a concern that there isn’t enough regulation. Similar reasoning applies to the explanation of the low performance and wide uncertainty expressed in the mixed central/devolved option. Assessments for this option referred to the possibilities for “huge polarisation” (UK policy-maker 1, #A115), “huge variability” (UK patient advocate 3, #A30), and “wider swings in opinion and regulation” (US patient advocate 5, #A1751) as a result of weak centralised oversight.

US perspectives on good governance under this issue revealed different framings of hESC research and the processes of governance in supporting hESC research as compared to UK perspectives. Criteria defined by US participants emphasise the quality of scientific outcomes as being dependent upon scientific autonomy and an indirect process of research support. However, the autonomy is different from that expressed in the US policy literature as discussed in Chapter 5. There, scientific autonomy was characterised by the need to leave scientists to determine the best outcomes to pursue, as suggested by the research. In the MCM interviews, US stakeholders defined criteria that

tend to be grounded in a firm belief in scientific autonomy, yet are more explicit in emphasising that ultimately scientific outcomes should be characterised by therapeutic aims. Thus, though autonomy is implied in, for example, the view that scientists should have “freedom to perform research” (US industry executive 1, #C346), this is countered by the sentiment that this type of autonomy is necessary *because of* the need to move towards therapeutic outcomes.

This area of research should advance medicine through its research... It’s certainly interesting to know about embryos, but I think everyone involved in this is involved in the advancement of medicine, not just abstract knowledge about biology (US bioethicist 5, #C246).

This criterion [‘advancing therapies’] reflects that there is an urgency and overriding moral authority to help people through this research and move the research towards clinical therapies (US professional body 5, #C233).

It is worth noting that criteria which express the desire for more therapeutic ends are more prominent among non laboratory-based scientists. Such points about inter-stakeholder differences will be taken up in the next chapter, but it offers early indication of the presence of differences between national perspectives on good governance, as well as within them.

In this more therapeutic framing of hESC outcomes, it appears that perspectives on good governance expressed by US stakeholders in the MCM interviews are diverging from the views on good governance under this theme in the US policy literature. This is seen both in the framing of the desired qualities of scientific outcomes, as well as in the rationales for why indirect processes of research support are needed to enable scientific autonomy. In regard to these latter areas, the criteria reflect a desire for an open and flexible space for science to advance within.

Any regime has to be at a level high enough to be able to deal with fast moving science. You can't have detailed regulatory regimes... [We need] flexibility that allows science to move forward even in light of political restraints (US professional body 3, #C256).

It is important to point out that this ‘flexible space’ is not presented as limitless, but rather is one that works with the science to support it. In other words, US stakeholders stress that with flexibility to ‘follow the science’, should come stability and consistency in the policy framework.

[This criterion] comes from working with other states and wanting to be able to share lines.... [It’s] about not impeding collaboration... [We want] uniformity and consistency across and amongst jurisdictions (US policy-maker 5, #C265).

Following from the analysis of the criteria that comprise the issue, we would expect to find stakeholders preferring options with governance frameworks that are more flexible, afford more freedom to scientists, and offer a stable environment for research. Thus, options such as the mixed central/devolved, ethics-led governance and expert-led framework have higher rankings overall (under the most favourable conditions), while the detailed centralised oversight, detailed expert oversight and, to a certain extent, the devolved authority options have lower rankings (even under the most favourable conditions).

The ethics-led governance and expert-led framework options are the two highest performing options under this issue for US stakeholders. The two options have minimal regulatory or institutional oversight, and participants believe that science could be most easily advanced because these options offered both flexibility and uniformity. The ethics-led governance option had a slightly lower ranking, though, which could be attributed to the dangers of too much flexibility.

It's almost too much flexibility ... Where I worry about having too much flexibility is on authorising derivation research⁸⁴ that might go beyond the pale, both violating ethical standards, but also creating a political backlash that would threaten the rest of the research.. (US professional body, #A1452).

This was counter-balanced by optimistic assessments relating to, for example, the expert-led and non-regulated nature of oversight that is specified within the option.

In addition to these higher ranking options, it is worth pointing out some of the reasons for the poor performance of the mixed central/devolved (the US-based) option amongst US perspectives. Although the optimistic rank of the option is fairly high, the ranking range also features high uncertainty and ambiguity and the lowest minimum rank. Under optimistic assessments, one participant describes his higher score as being down to the simple fact that “it is able to be done in the end, even though the federal restrictions are in place. With your own money you can do anything” (US scientist 4, #A1679). However, under pessimistic conditions, the “lack of harmonisation makes it difficult to figure out how the policies would move forward on a broad scale... it’s hard for people to know what they’re supposed to follow” (US industry executive, #A1685). Finally, we might also briefly reflect on the lower ranking amongst US perspectives of the UK-based option, detailed centralised oversight. Though the UK has one of the most permissive climates for hESC research in the world, it is also one of the most heavily

⁸⁴ In this quote the participant refers to ‘derivation research’. This is a technical term referring to the first step in hESC research where the embryonic stem cell lines are actually *derived*, that is, the embryo is destroyed.

regulated. US participants aired concerns that regulation and centralisation would impede scientific autonomy by creating barriers to conducting research. They were also concerned about the regulatory implications for commercialising future hESC therapies.

6.2.3 Discussion

We can now answer the questions posed at the beginning of this section in turn. The criteria that comprise the issue being analysed here do differ between US and UK stakeholders. Moreover, the analysis of the criteria reveals different framings and perspectives on good governance under the theme ‘advancing scientific and technological issues of hESC research’. The table below summarises the prominent patterns of this aspect of good governance when we compare the UK and US stakeholders and the UK and US policy literatures:

Table 6.2. Summary table of patterns under the theme ‘advancing scientific and technological issues in hESC research’

		Perspectives from US policy literature vs. US stakeholders	Perspectives from UK policy literature vs. UK stakeholders	Perspectives of US stakeholders vs. UK stakeholders
Advancing scientific & technological outcomes & related issues in hESC research	Quality of scientific outcomes (including therapeutic & technological developments)	Slight Divergence	Slight Divergence	Slight divergence
	Processes of research support	Broadly congruent	Broadly congruent	Noticeably divergent

Shading Key

	<i>Noticeably divergent: Distinct differences across the two perspectives are clear and readily identifiable</i>
	<i>Slightly divergent: Some differences across the two perspectives are clear. Similarities or unclear signals exist.</i>
	<i>Slightly convergent: Some similarities across the two perspectives are clear. Differences or unclear signals exist.</i>
	<i>Broadly congruent: Similar patterns across the two perspectives are clear and readily identifiable.</i>

As can be seen in the table, a picture is emerging of the patterns in perspectives on good governance amongst UK and US stakeholders and the policy literature (as reviewed in Chapter 5) for this theme. Overall, both UK and US stakeholder perspectives emphasise the need for governance to create a space in which science can progress, but the characteristics and purpose of this space vary, as well as the nature and quality of scientific outcomes within it. UK participants tend to characterise scientific outcomes both in terms of *therapeutic and basic research outcomes*, but believe

outcomes are best pursued within a *supportive regulatory environment* that is ‘enabling’ of science and fosters public trust. US stakeholder perspectives are grounded in a belief in scientific autonomy within a *flexible and harmonised environment*, yet a majority of participants still emphasise the importance of *therapeutic outcomes* being an eventual aim.

These findings highlight a distinction between stakeholder perspectives and the policy literature in relation to the characterisation of scientific outcomes. UK policy documents tend to reveal a therapeutic framing of hESC research outcomes while US policy documents tend to adopt a framing that emphasises scientific autonomy. However, the elements of research support are similar in both stakeholder-based and policy document-based perspectives in the case of each country. In the UK, the emphasis is on direct processes of research support, such as targeted regulatory support and state-led standard-setting initiatives, whereas in the US more indirect processes of research support aim to create a flexible space in which science can advance autonomously.

The differences in framing between stakeholder perspectives and across the policy literature are all the more intriguing given the fairly similar patterns observed in the overall rankings of the governance options. This serves to underscore the point that in understanding *how* the perspectives on good governance are characterised and constituted, we can begin to gain an appreciation of their importance in a comparative context. The next section will now look at perspectives within the theme ‘establishes appropriate institutions and instruments of governance for hESC research’.

6.3 Institutions and instruments of governance for hESC research: qualities of deliberative activities

6.3.1 Introduction

In Chapter 5, a variety of governance institutions and instruments that are discussed in the UK and US policy literature were analysed and a number of elements of good governance identified. In the UK policy literature, it was found that good governance tended to be characterised in institutional terms by strong regulatory mechanisms and centralised, national institutional oversight. In the US policy literature, good governance tended to be characterised by flexible funding policies nationally and local institutional oversight. Perspectives on good governance in the UK seemed to

emerge through a focus in the first instance on the *processes* of governance and how specific processes are best able to lead to desired ends, or outcomes. In the US policy literature, by contrast, perspectives on good governance tended to be characterised by a primary focus on the *outcomes* of governance, followed by a discussion of the processes through which these outcomes might be achieved.

The relative focus on outcomes over processes, or vice versa, may have important implications for the ways in which policy strategies are deployed and stakeholder-specific influences affect them. Because of this, they will be more fully discussed in the cross-cutting discussion of the empirical findings in Chapter 8. For the present discussion, though, whether the characterisations of good governance are process-based or outcome-based, is only one element of the wider issues under this theme of good governance. As introduced previously for the context of this thesis, ‘deliberation’ refers to the ways discussions are conducted and decisions made within a governance system. These can occur at a formal or informal level, thus echoing the definition adopted by Fineberg, et al (1996) and introduced in Chapter 3:

any formal or informal process for communication and for raising and collectively considering issues... In deliberation, people confer, ponder, exchange views, consider evidence, reflect on matters of mutual interest, negotiate, and attempt to persuade each other (ibid., p. 73).

Building on this, important factors to consider in analysing the quality of deliberations include the nature of the inputs and interactions to decision-making that take place, the roles of the actors engaged, and the (perceived) successes or failures of the outputs (e.g. policy-making) that result. In all of this, from the term ‘quality’ all the way through to determinations of ‘success’ and ‘failure’, it should be clear that the perspectives themselves will be critical to the analysis and the ways in which the qualities of deliberative activities are defined, perceived and evaluated.

Criteria related to the qualities of deliberations were the second most frequently mentioned by all participants across the perspectives. However, distinctions were made about different types and/or qualities of deliberative activities, so two main analytical issues will be pertinent to this analysis. First is the role of the public and its perceived importance in contributing to – and participating in – deliberative activities. Second is the nature of expertise and its relationship and interactions with other features of good governance. Each analytical issue is defined as follows:

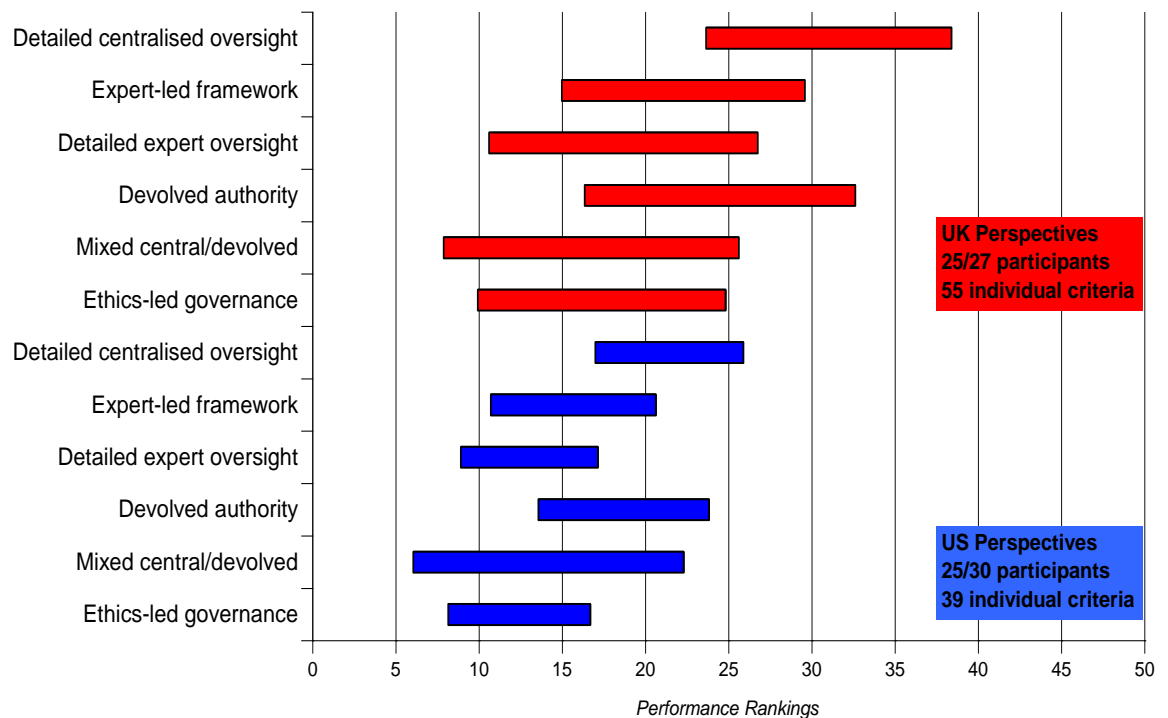
Role of the public: *Criteria in this issue are concerned with how the role of the public is conceived of and defined as a part of good governance. The focus is both on how public inputs and deliberations might feed into the governance*

process, if at all, as well as the importance of public views on the institutions and instruments of governance itself. Thus, issues like public trust and confidence are addressed.

Nature of expertise: *Criteria in this issue are concerned with the features and characteristics of expertise within the governance framework. They focus on issues like the composition of expert bodies, the quality of advice that is provided, the types of deliberations that occur, and the qualities of the processes of input themselves as they reflect on the wider role of expertise in a context of good governance.*

In presenting these two issues for analysis, we do not intend to claim these are the only elements of deliberative activities worth considering. For example, one could also include ‘formal decision-making’, such as legislative procedures. However, due to the volume of data collected for this research, a full analysis of every single line of inquiry cannot be presented here. These two types of criteria are believed to be most relevant to the main hypotheses being tested in this thesis and have the greatest potential to contribute to ongoing academic discussion. However, before considering each in the sections below, we will briefly consider the performance rankings of both issues combined under the broader heading ‘qualities of deliberative activities’ to give an initial indication of the key areas of analytical inquiry.

Figure 6.3. Rankings under UK and US perspectives for the issue ‘qualities of deliberative activities’



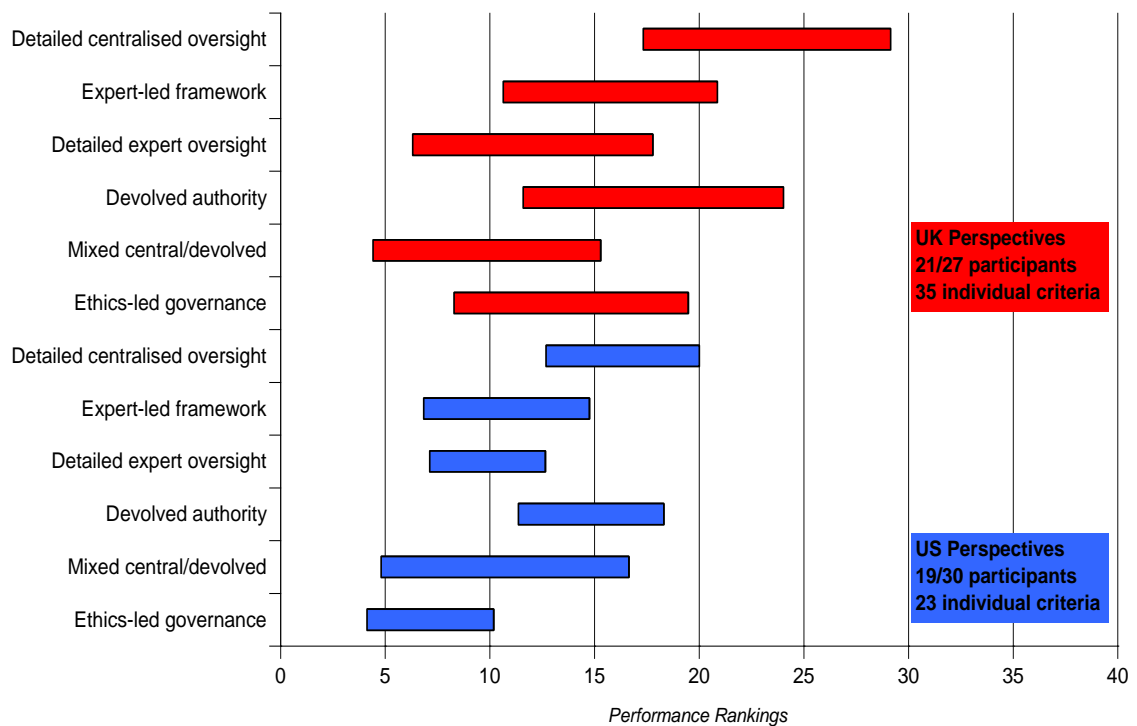
As Figure 6.3 shows, there are some patterns to be found in the rankings. For example, the ‘stair-step’ pattern of the first three options holds under both perspectives

and is consistent with the pattern found in the overall rankings under each perspective (as shown in Figure 6.1). In addition, proportionally more UK-based participants define at least one criterion in this issue than US-based participants, indicating a distinction in emphasis between the two perspectives. This is supported by the mean weightings between the two stakeholder groups: 38% and 24% for UK and US perspectives, respectively. It is worth pointing out not only the greater importance given by UK perspectives to these types of criteria over the previous ones ('advances the science') but also the lesser importance given by US perspectives in comparison to both UK perspectives and the previous group of criteria.⁸⁵ This reveals a potentially significant contrast between the two perspectives and the way features of good governance are characterised. We will now unpack this finding further and look at how these evaluations and rankings might differ in relation to the two 'sub-issues' defined above.

6.3.2 Deliberative activities: the role of the public

The analysis of the UK and US policy literature with regard to this topic showed that although there was acknowledgement of the importance of public engagement and participation in both sets of policy documents, there was very little critical reflection on what this engagement would look like in practice or how (e.g. in what ways) one would know that the outputs of any exercises had been incorporated within policy-making processes. Given this, it is interesting, but perhaps not surprising, to find that the role of the public as an element of good governance was brought up by a majority of the participants interviewed. However, there is an important difference in the way the issue was addressed in each country, with a greater relative percentage of UK participants defining this type of criteria (35 criteria defined by 21 UK participants) and a higher mean weighting of 24% attributed to it. In contrast, only 23 criteria of this type were defined by 19 US participants, with a mean weighting of only 13%. The implications of this will be explored throughout the analysis below. Looking to the picture of performance shown in Figure 6.4 below, we can see that the ranking patterns under this issue are fairly similar between the two perspectives, although there are some notable differences.

⁸⁵ Again, the reader is referred to Annex I for a table directly comparing all the weightings and criteria types analysed in this chapter.

Figure 6.4. Rankings under UK and US perspectives for ‘role of the public’ criteria

First, UK participants seem to express a greater degree of either uncertainty or ambiguity under this issue, as indicated by the relatively longer length of the ranking bars compared to US interviewees. More detailed analysis⁸⁶ shows that this is due to in part to a slightly greater use of uncertainty in the assessments compared to US participants, but is more prominently attributable to a higher degree of ambiguity expressed among UK participants across the options. Recall that ambiguity is a feature of disagreement between participants, so it does suggest that there are particular features of this type of criteria which are more affected by individual framings or points of view.

Second, though the ranking patterns for both perspectives are roughly similar for the first three options (although there is a difference in the pessimistic ranking of the detailed expert oversight option), the second three options (devolved authority, mixed central/devolved and ethics-led governance) display different patterns across the two perspectives. Third, under US participant assessments, the mixed central/devolved option has a greater range of uncertainty and ambiguity⁸⁷ relative to the other options, whereas for UK perspectives it is one of the first times we do not see such a wide range expressed for this option. Finally, there is a distinct difference in the evaluation of the ethics-led governance option between both national perspectives. This is intriguing

⁸⁶ These charts and related analysis are shown in Annex I.

⁸⁷ Further analysis presented in Annex I confirms that the longer range seen in the rankings is a factor of both greater uncertainty expressed and ambiguity reflected for this option among US participants.

given that within the definition of this option there is no specified role for the public. Therefore, it will be interesting to see how UK and US participants differ in their interpretation as to which aspects of the option fulfilled criteria about the ‘role of the public’ in this regard.

Analysis of the criteria that comprise this issue reveals differences in the ways in which the role of the public is characterised. These differences cut across both perspectives. Criteria may be characterised in terms of the *processes* of public engagement or participation activities and the qualities which make them ‘good’. These criteria variously address how a ‘space’ for public deliberation should be created, what the role of society should be in “setting the guiding principles” for research, and the need for there to be “opportunities to express views” (UK scientist 3, #C196), including what the nature of these views might be, such as “morality, religion and ethics” (US scientist, #C284). Alternatively, criteria in this issue may be characterised in terms of ‘publicly framed’ *outcomes* that might arise from good governance. In other words, these criteria draw on various features of good governance such as ‘transparency’, ‘acceptability’ and ‘legitimacy’, but present them as necessary features to ensure outcomes that are framed *in relation* to the role of the public or public perception. These outcomes are most notably (and frequently) concerned with public trust.

Different emphases are placed on each of these features of the criteria across the two perspectives. Amongst UK perspectives, there is a greater emphasis on how governance *processes* can lead to public trust as an *outcome* of good governance. In this, many criteria relate to the reasons for employing various mechanisms of public engagement or participation activities *because of* the need to foster public trust. In the words of one participant, the governance option “has to engage with the general public in order to avoid mistrust. It has to represent all opinions, not to edit what gets presented at the end” (UK professional body 4, #C331). Others discuss the need for an active role by government where, “in terms of effective governance, it’s about government promoting public confidence” (UK regulator 4, #C118). In this sense, public trust is gained through active demonstrations to the public. The role of the public, then, is to hold government accountable for this task.

Though the majority of criteria in this issue are instrumentally⁸⁸ focussed on gaining public trust, some are more reflective on the qualities of engagement processes,

⁸⁸ See the discussion in Chapter 3 (p. 52-53) and future discussion in Chapter 8 (Section 8.2) for the theoretical context in which this term is used.

usually without reference to any particular ends being achieved as a result. Thus, they reveal a more normative⁸⁹ framing of how things ought to happen. One participant defined a criterion of principle, “representation”, to this end. She felt that a governance framework would be unacceptable if it did not include full and appropriate public representation. She ruled out the detailed expert oversight option on the basis that it did not have a clear mechanism for public engagement. Another commented more on the process of how the governance system should account for public views:

[The criterion], ‘responsiveness’ is about the readiness of the regulatory system to engage with the stakeholders, so there is an ongoing dialogue and a constant updating of the people’s concerns and interests. Also that the regulatory system has a willingness ... a willingness to listen and engage and respond rapidly where it is required (UK bioethicist 1, #C152).

This statement not only illustrates a more normatively motivated criterion about the role of the public, but also addresses some of the earlier inadequacies in the ways the UK policy literature dealt with public consultation and engagement. As was argued in that discussion,⁹⁰ the literature fails to comment on how public views are taken into account. That is, although statements are made about the importance of ‘being seen’ to take public views on board, they are lacking in critical reflection as to how this would be done and, perhaps more crucially, how the public would know it had been done.

This point is worth further examination. Though not always couching them in such ways as the previous example, some UK participants did reveal normative considerations about the processes of appraisal in their discussion of the potential pitfalls of public engagement and consultation. We note two examples in relation to the option analogous to the UK, ‘detailed centralised oversight’.

It [public engagement] can be done on an alarmingly small scale. So I do have concerns it isn’t done robustly enough (UK professional body 4, #A1909.)

The option [assessment] is very mixed. You have to be quite determined to have your voice heard and keep the debate open. [But] it’s certainly not closed to public debate (UK bioethicist 2, #A1034).

Though ‘good’ engagement was defined slightly differently by each of these participants, they all shared the belief that the important thing was that it happened robustly and with broad inputs. In this sense, the empirical findings are similar to the perspectives identified in the policy literature, but with a stronger sentiment about the importance of public trust coming from the empirical findings.

⁸⁹ As above, see discussion in Chapter 3 (p. 52-53) and future discussion in Chapter 8 (Section 8.2) for the theoretical context in which this term is used.

⁹⁰ See the discussion in Chapter 5, p. 117-120.

We commented earlier on the high ranking of the ethics-led governance option under this issue for UK-based stakeholders, despite the fact that this option does not include any provisions for public involvement in the same ways as the other high-ranking options under this issue (the devolved authority and detailed centralised oversight). It seems that many UK participants believe that the ethics-led option would score well because it had a ‘shared vision’ developed by a national bioethics body. Implicit in this assessment is the idea that the simple presence of a bioethics body corresponds to a full consideration of social and cultural views. One participant commented that despite the fact there was “very limited engagement and scrutiny and very little involvement with anyone but scientists”, one still had to think that there would be “a lot of public confidence if everyone signs up to the rules at the top” (UK bioethicist 4, #A678). Another participant based his assessment on his view of how a bioethics committee deliberates, commenting they would “take into consideration what the public thinks about by their very nature” (UK scientist 6, #A1818).

These assessments lead to an interesting insight into the perceived role of bioethics committees. In Chapter 5 it was argued they have come to serve as a ‘new mode’ of expertise, which is assumed to be more representative of the public by virtue of their ability (or mandate) to reflect on the shared moral and ethical values of a society. However, there are questions as to whether and by what evidence these claims are held to be true. The findings here suggest that these claims may be quite uncritically adopted by some stakeholders. Further comments will be made on this in Chapters 8 and 9 where empirical, theoretical and normative implications are explored, but the issue is important to raise here.

While the UK perspectives seem marked more by a concern with how to gain public trust through good governance, the US perspectives tend to focus on the mere presence of public engagement and the types of *policy* outcomes (not necessarily framed in relation to the public) it might lead to.⁹¹ One US participant defined the criterion ‘space for public deliberation’, which expressed his belief that such a space was important to create “with a politically and socially charged issue such as this one” (US regulator 2, #C83). Another participant commented that there should be “an opportunity for public discourse that’s real... [where] public discourse is actually taken into consideration” (US bioethicist 3, #C39). These criteria seem to reveal a dissatisfaction

⁹¹ There were comparatively fewer criteria about public trust as one outcome of engagement, only 7 out of 23 criteria for US participants as compared with 16 out of 35 for UK participants.

with current governance in the US and a perception that there is no real opportunity for public input. Thus, any public input will certainly lead to better governance outcomes.

However, there is a tension exposed between the desire to create a public space for discussion and the perceived dangers of including all the views that might be present in a culturally diverse society.

I'm not looking for totally democratically representative input. Not everybody needs to be represented in the system. We need people as part of the process who have something to contribute to the process. They're contributing skills or knowledge... (US professional body 3, #C259).

Similarly, another participant commented that society needed to be involved in setting the standards and guiding principles for research, but society only as represented by political bodies (US scientist 4, #C287).

These criteria presented themselves in interesting ways in the option assessments. The three options that specifically stated there were provisions for public involvement within their definitions (the detailed centralised oversight, devolved authority and mixed central/devolved options), all had similar optimistic rankings, but there was a longer ranking range for the mixed central/devolved option. This latter finding was brought up earlier and analysis here seems to suggest it could be attributable to the tension discussed above. The public may have more input within 'individual jurisdictions', but this could be interpreted positively or negatively. As a result, participants used a wide scoring range, in some cases utilising the full range of their chosen scoring scales.

Since it was discussed earlier, it is worth briefly commenting on the ranking of the ethics-led governance option under US-based assessments. As we have seen, the US perspective on the role of the public is more focussed on the processes of engagement. The ethics-led governance option does not have engagement mechanisms and so most participants felt that because there was "no real avenue for participation" (US industry executive 2, #A1273), it would "lack credibility" (US professional body 3, #A1470) and would not be "open to democratic mandates" (US industry executive 1, #A2010).

In summary, under both national perspectives there is concern with the role of the public, but for UK perspectives the concern seems more motivated by a desire to ensure public trust is established as an outcome of good governance, while for US perspectives the concern seems more to do with ensuring good, democratically-based policy outcomes. However, 'democratic' was not always used in a normative way, but instrumentally to ensure that individual policies, and wider governance approaches,

reflected the views of the majority. We will now look to the second component of this sub-theme, the nature of expertise.

6.3.3 Deliberative activities: the nature of expertise

As has been discussed previously, the role of expert input and advice is a necessity when developing policies for new and uncertain technologies – though sometimes problematic in the way it is articulated or interpreted. In Chapter 3, the views of various academic theorists were discussed concerning how technocratic decision-making might be characterised in a context of ‘good’ governance. Amongst other insights, it was argued that if expert input was combined with principles of transparency, democratic deliberation and participatory mechanisms, it might be able to overcome some of the pitfalls that academic analysis has highlighted over the years (see, for example, Jasanoff, 1990).

In Chapter 5 we looked at the perspectives of the UK and US policy literature on the role of expertise in good governance. In the UK, balanced representation of experts and the inclusion of lay members on expert advisory panels were seen as fundamental components of ‘good’ expertise. In the US policy literature there was discussion about including public views on oversight panels, but there was little guidance as to how these members should be selected or who they should be. While there is similarly little guidance on selection criteria, per se, in the UK policy literature, the proportions of expert versus lay members are explicit in the Human Fertilisation and Embryology Act, although the selection criteria for other expert bodies are more opaque.

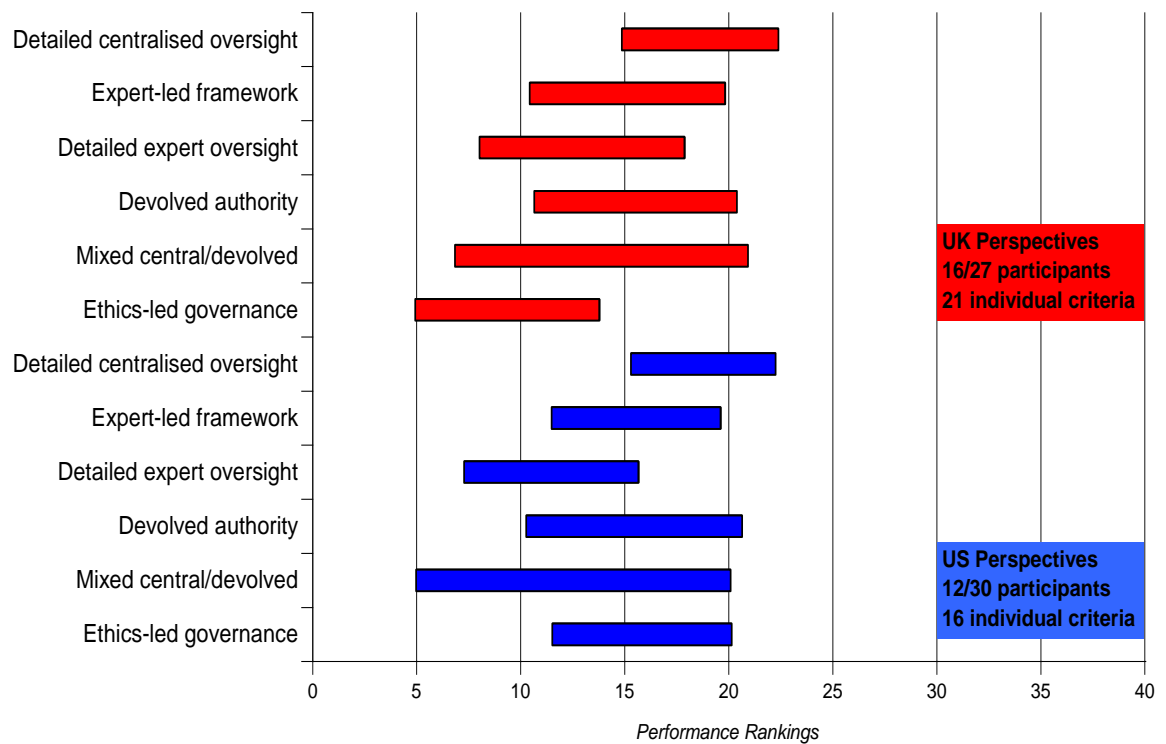
Figure 6.5 below shows the ranking patterns for the UK and the US under the issue ‘nature of expertise’. On the face of it, there is a much greater degree of similarity between US and UK rankings with regard to this issue than for the previous one (with the exception of the ‘ethics-led governance’ option⁹²). However, we can immediately see there are fewer criteria defined within this issue among both groups of stakeholders. This means we might be more cautious about any interpretations made.

Under these criteria we find relatively equal weightings across the two perspectives. While US participants expressed a similar mean weighting to those under the ‘role of the public’ for these criteria, 11%, UK perspectives expressed a relative

⁹² As was discussed in Footnote 32, p. 71, this is an example of where there were insufficient participants evaluating this option to merit full and robust analysis of the implications arising from this ranking difference.

importance of 15%, which is lower than the weightings under the previous issue. Despite the caveat about low criteria within the issue, the weightings do seem to confirm a lower priority assigned to this aspect of deliberative activities within each national perspective.

Figure 6.5. Rankings under UK and US perspectives for ‘nature of expertise’ criteria



Under UK perspectives, half the criteria in this issue focussed on the composition of expert advisory bodies. The overriding concern is that expertise be multi-disciplinary and representative of wider society. In the words of one participant, “expertise should be broad, not reliant on a narrow scientific view, and should have different perspectives on the potential benefits, such as social benefits” (UK policy opposition 1, #C130). Another participant echoed this, defining expertise as “people who have knowledge of the different areas that you might want to take into account” (UK patient advocate 4, #C180). These different areas included ethical, scientific, clinical and lay knowledge. This composition was analogous to that discussed by other participants defining similar criteria.

It is worth calling attention to the criterion discussed above by the participant who is opposed to some or all aspects of hESC research policies. While she defines a criterion which is, at face value, similar to those defined by other UK-based

participants, another participant who opposes hESC research policies describes his views on expertise in the following way:

membership of decision-making bodies is often dominated by scientists or people who are other experts who get to be on these bodies because they have adopted the scientific worldview and discourse, meaning a set of assumptions that scientific research equals progress and more knowledge is always a good thing. It is this scientific ‘expertocracy’ that is a travesty and prevents any kind of real broad-ranging attempt to think about the issues that this type of research raises (UK policy opposition 6, #C343).

Though this latter example reflects a particularly strong conviction, it is still expressing a similar point about the importance of including breadth of input and ensuring representativeness of diverse points of view. The examples show that even those on ‘extreme’ ends of the policy debate can find common ground. In addition, the perspective seems similar to the views expressed in the academic literature about the need to open expert-based processes in order to mitigate the risks of singularly technocratic inputs to decision-making.

While lay involvement was often mentioned as ‘another’ type of expertise, it was not emphasised as heavily by UK stakeholders as it was within the UK policy literature. Rather, it was only one feature of many that should be considered. Moreover, though acknowledging its importance, there was an air of dissatisfaction with the term ‘lay’. One participant felt that in including lay members on scientific committees like the HFEA, governments actually ran a greater risk of having the decision-making process captured by one particular scientific or disciplinary point of view (UK scientist 6, #C315). This was because when lay people were included, there were less places at the table for a range of experts. Others commented that lay expertise was a fleeting concept because as soon as one joined a committee, he quickly became an expert.

In rankings under this issue, options with stronger centralisation, some type of regulation and a balance in expert and public deliberation components all perform more positively. The mixed central/devolved option has the widest range of uncertainty under UK perspectives, but one of the highest optimistic rankings of all the options. This is particularly interesting because this option has (under UK perspectives across all issues discussed thus far) been consistently assessed more pessimistically, with lower rankings and higher degrees of uncertainty and ambiguity. Here, though, participants interpret the devolved feature of the option to mean there might be more opportunities for broad expertise to play the ‘right’ kind of role in deliberative activities. “It’s more empowering at the devolved level. But it will depend...on the resources and information

available to those at the devolved levels” (UK policy opposition 1, #A721). Another felt that the presence of two levels of governance (centralised and devolved), meant that there would be “strong expert engagement across all areas... (like having) two levels of Parliaments in these options” (UK bioethicist 1, #A816). Thus, unlike the mixed central/devolved option, the devolved authority option resulted in a lower expression of uncertainty/ambiguity due to the clearer delineation between devolved and centralised oversight within the option.

US-based perspectives are similar in some ways to those of UK-based participants, but as with the previous issue, there are subtle differences and nuanced tensions. Most criteria within the issue are about the ways in which the processes through which expert-based inputs to policy-making occur. Criteria of this type define *how* expert input should occur in relation to its intended *purpose* (as perceived by the participant) in a wider governance context.

Expertise is extremely important so that the laws can be realistic for what the science is doing, not just a way to scare the public. The policies need to be legitimate for what could happen (US scientist 5, #C62).

Here the purpose, or outcome, of expert input is legitimacy in policy-making, which the participant implied was not happening. Others express similar concerns that the right ‘outcomes’, such as ‘objective’ decisions based on ‘testable knowledge’ (US bioethicist 4, #C279), are not being realised because of poor types of expert input.

No policy or scientific decision should be made without the input of all experts in hESC research present and with a voice in the conversation. You have to have highly trained, currently practicing scientific experts in the room at all times, especially for ethics review... Furthermore, we should have no clergy on the board, [we need] more scientists, more experts (US professional body 5, #C229).

We need immunity of the deliberations to political influence versus scientific leadership. It's about the scientific integrity of the deliberations... Objectivity is relevant here (US industry executive 4, #C296).

Even criteria less explicitly critical reveal a tendency to emphasise the way expert input is given *in relation* to the purpose. For example, some criteria discuss the need for a balance between expert and societal views in expert decision-making, where ‘societal’ views are often equated with ‘ethical’ inputs. This ties in with discussions about ethical deliberations being a part of the governance framework.⁹³ However, the motivations for defining these criteria seem to be aimed at ensuring ethical deliberations occur, not as a normative feature of governance, but rather to portray the science as a ‘professional’ discipline, capable of policing itself.

⁹³ See the discussion of this point in Chapter 8, Section 8.3.

These types of nuances offer a partial explanation of why the detailed expert oversight does not score highly under US perspectives for these criteria, despite the fact the option relies so heavily on expert input to governance. The option does not specify a role for the wider public and so is perhaps perceived to be lacking in societal balance. One could say this reflects the original definitions of the options themselves, as they are worded in ways that might be interpreted to limit the types of expertise that are a part of the governance process. However, there was evidence of critical reflection across all the options on the ways in which the nature of expertise could vary, even within the constraints of the option definitions, so we feel more confident this was not the case.

In summary, there are different types of criteria that characterise the sub-theme of ‘nature of expertise’. These criteria reveal subtly diverging perspectives between UK and US stakeholders. UK perspectives are characterised by a concern over how broadly composed expert bodies are so good and balanced processes of expert input will ensue. With the emphasis on people and process, legitimate and evidence-based advice will ultimately occur. US perspectives reveal a different focus, with good input being the primary concern. There is a greater focus on which processes will enable the right outcomes and a lesser focus on the types of people required. As a result, a tension is revealed between the desire to have positive outcomes for one’s policy agenda and the need for democratically representative and balanced input. Thus, we might propose that the UK perspective tends to believe that having the right *people* will lead to the right *processes* of governance, while the US perspective tends to believe the right *processes* are needed so that the right *outcomes* result.

6.3.4 Discussion

Table 6.3 below summarises patterns in US and UK stakeholder perspectives and the respective policy literatures on good governance in relation to the theme of good governance ‘establishes appropriate institutions and instruments for hESC research’.

Table 6.3 Summary table of patterns in perspectives for the theme ‘establishes appropriate institutions and instruments for hESC research’

		Perspectives from US policy literature vs. US stakeholders	Perspectives from UK policy literature vs. UK stakeholders	Perspectives of US stakeholders vs. UK stakeholders
Establishes appropriate institutions & instruments for hESC research	Qualities of deliberative activities: publics	Slight divergence	Slight divergence ⁹⁴	Slight divergence
	Qualities of deliberative activities: expertise	Slight convergence	Broadly congruent	Slight divergence

Shading Key

	<i>Noticeably divergent: Distinct differences across the two perspectives are clear and readily identifiable</i>
	<i>Slightly divergent: Some differences across the two perspectives are clear. Similarities or unclear signals exist.</i>
	<i>Slightly convergent: Some similarities across the two perspectives are clear. Differences or unclear signals exist.</i>
	<i>Broadly congruent: Similar patterns across the two perspectives are clear and readily identifiable.</i>

We can see that there is a divergence in the way institutions and instruments of governance are characterised. UK stakeholder perspectives seem to emphasise the idea that putting the right processes in place will, necessarily, lead to good governance outcomes. Perspectives on the role of the public are characterised by the idea that public engagement processes, or indeed general mechanisms of government, should be conducted because they will foster public trust. Putting the right balance of individuals on expert bodies will mean the bodies might function in a way that is robust. Either way, good processes will lead to good outcomes.

In contrast, US stakeholders reveal a set of framings more focussed on the outcomes of good governance. The perception that greater public input into deliberations is needed seems less motivated by a desire to see public discourse as a normative good, and more instrumentally motivated by a desire to see particular policy agendas advanced. Similarly, the way expert input is conducted is expressed in relation to the purpose it ‘should’ achieve. This seems to reveal a tension in the motivations of US participants in this area. Though there is a shared focus on outcome-based policy approaches, there is an inherent tension in the ways in which these outcomes might be achieved amongst different stakeholder groups. This is explored in the next chapter.

Throughout the preceding sections, normative, instrumental or substantive motivations have been pointed out where relevant. While a full analysis of these

⁹⁴ Though the patterns are identified as divergent, this is mostly due to the fact that there was a strong tendency to equate the role of the public with public trust under UK stakeholder perspectives. This feature was notably absent from the perspective identified in the UK policy literature.

motivations as criteria, themselves, is reserved for Chapter 8, their relevance to the discussion here can, and should, be explored. An examination of the findings above in light of the types of imperatives (either normative, instrumental or substantive), reveals some distinct patterns, both qualitative and quantitative,⁹⁵ between stakeholder groups.

First, normative values about the nature and quality of deliberations emerge which relate to good processes and features of deliberations as ends in themselves. For UK perspectives, criteria such as openness, transparency, and breadth of representation (both in terms of public engagement and expert advisory processes) tend to be of great importance and seem to be ways of expressing normative democratic values of deliberation. Normatively derived conceptions of the *legitimacy* of the governance process become linked to, and follow from, the implementation of these features. That is, when the process is seen to reflect normative values, it is variously described as more ‘consistent with public opinion’ (various participants, #C339, #C176, #C340) , ‘objective’ (various participants, #C345, #C135, #C197, #C174), ‘accountable’ (various participants, #C120, #C9, #C205, #C148) and, perhaps, legitimate.

The US perspectives are more difficult to disentangle. Though there are normative imperatives identified within the criteria, it is less clear whether a common theme underpins them. Normative values about the processes of deliberation are expressed in different ways, either through criteria about minimising political influence and respecting the democratic process (various participants, #C164, #C249, #C232, #C41, #C42, #C209), creating a space for public input and discourse (various participants, #C284, #C251, #C39, #C84, #C83) or striking a balance between the role of expertise and societal values in decision-making. These findings do seem to expose a tension between the desire for science to advance and the views of a pluralist society to be respected. Legitimacy, then, seems more in the eye of the beholder and based on individually held normative values about democracy and pluralism.

Instrumental imperatives are revealed under the perspectives that relate to gaining public trust and realising scientific goals. The latter was described in Section 6.2 above. Trust is a particularly dominant theme among UK perspectives, as we have shown throughout the analysis. It is discussed in various ways, indicating that participants interpret trust according to their own set of assumptions and framings, not

⁹⁵ These patterns were tested by defining an issue and generating performance rankings under two MCM ‘issues’: ‘deliberations (normative)’ and ‘trust (instrumental)’. These charts can be found in Annex I.

those which might be publicly deliberated and, hence, more substantive in nature.⁹⁶ Overall, an instrumental UK perspective seems to emerge in both emphasising the *need* for public trust as an important component of good governance, as well as describing the *ways in which* public trust and confidence can be achieved. Of this latter group, trust is seen as arising from various governance features, such as regulatory oversight, centralised decision-making, transparent policy mechanisms and representativeness.

Two points are worth commenting on further. First is the identification of ‘representativeness’ as both an instrumental and a normative issue within the discussions here. With some participants it reveals normative ideas about how the process ought to work, whereas with others it reveals an instrumental motivation to obtain public trust as a singular, privately-held, outcome of balanced representation. MCM analysis allows us to expose these different framings. The second point relates to arguments discussed in earlier chapters⁹⁷ that the basis of trust (or public accountability) in the UK was seen to rest upon the types of experts who are at the centre of socio-political governance processes. The empirical findings here do not necessarily support this view. Further comments will be made on this in Chapter 8.

Trust as an instrumentally motivated consideration was less frequently found for US perspectives and thus the analysis here is more tentative. Of those criteria that do reveal instrumental imperatives about fostering public trust, they focus primarily on the actions of policy-makers in their role of ensuring public safety. A few participants mention the role of education in helping to promote awareness about how the science was being conducted safely and what the purposes of the science were (that is, the therapeutic and scientific goals it was working towards). Thus, there is a parallel here with work in the public understanding of science literature.⁹⁸ This indicates that though much work has been done outlining the problems with a simple ‘public education = public acceptance’ equation, there is further work to be done.

6.4 Conclusion

Returning to the main hypotheses that were set out at the beginning of this chapter, we can conclude that 1) it is indeed possible to discern discrete perspectives on

⁹⁶ See the discussion in Chapter 8, Section 8.2.

⁹⁷ See the discussion in Chapter 5, p. 120-121.

⁹⁸ We make this point to indicate we are aware of the parallels, but this body of literature is not directly discussed within this thesis. See in particular (Irwin and Wynne, 1996).

good governance between and within different groups of stakeholders in the US and the UK; 2) regularities in the ways in which perspectives on good governance are constituted have been identified and analysed, with certain patterns emerging as summarised in the table below; 3) as a method of empirical analysis, MCM has allowed us to develop an understanding of how these perspectives are constituted in an open, reflexive, transparent and verifiable manner; and 4) comparisons between the two national settings show notable differences between stakeholder perspectives and policy literatures concerning the nature of good governance. Table 6.4 below provides a summary of the key patterns identified in this chapter.⁹⁹

Table 6.4. Summary table of patterns in perspective across all themes

		Perspectives from US Policy literature vs. US stakeholders	Perspectives from UK Policy literature vs. UK stakeholders	Perspectives of US stakeholders vs. UK stakeholders
Advancing scientific & technological outcomes & addresses related issues in hESC research	Qualities of scientific outcomes	Slight divergence	Slight divergence	Slight divergence
	Research support processes	Broadly congruent	Broadly congruent	Noticeably divergent
Establishes appropriate Institutions & instruments for hESC research	Qualities of deliberative activities: publics	Slight divergence	Slight divergence ¹⁰⁰	Slight divergence
	Qualities of deliberative activities: expertise	Slight convergence	Broadly congruent	Slight divergence
Identifiable social & cultural bases of good governance emerge	Bases of trust and legitimacy	Commented on in Section 6.3.4 above		

Shading Key

	<i>Noticeably divergent: Distinct differences across the two perspectives are clear and readily identifiable</i>
	<i>Slightly divergent: Some differences across the two perspectives are clear, but similarities or unclear signals exist.</i>
	<i>Slightly convergent: Some similarities across the two perspectives are clear, but differences or unclear signals</i>
	<i>Broadly congruent: Similar patterns across the two perspectives are clear and readily identifiable.</i>

⁹⁹ This table is a replication of Table 6.1 presented earlier, but with the sub-themes and themes not analysed in this chapter removed for purposes of clarity.

¹⁰⁰ See discussion in related section(s) for caveats.

As the summary table shows, this chapter has analysed stakeholder perspectives on good governance in the US and the UK under a number of previously identified themes of good governance. In particular, some systematic contrasts have been found that distinguish key elements of perspectives in the US and the UK. This is most notable in two places. First, there is a distinct tendency for US and UK stakeholders to adopt contrasting perspectives on how good governance can best facilitate and foster advances in the science. US stakeholder perspectives on good governance tend to characterise the facilitation of hESC research in terms of creating a *flexible, harmonised space* within which the science may advance in a relatively autonomous fashion. UK stakeholder perspectives on good governance, on the other hand, tend to frame the facilitation of hESC research in terms of the construction of a *regulated, protected framework* around which the science can advance in a relatively structured fashion.

Second, there is a difference in perspectives on the qualities of deliberative activities. UK stakeholders tend to characterise deliberative activities in a *process-based* way, with specific outcomes dependent on these processes. US stakeholders tend to characterise these activities more directly in terms of the *outcomes* they might achieve. While good processes of public engagement and other mechanisms of governance are seen as key to *establishing public trust* by UK stakeholders, US stakeholder perspectives expose a *tension* between the importance of assuring broad public input and expert, or evidence-based, deliberations among expert advisory bodies. Some US stakeholders believe ‘real’ public input and representative, reflective expertise should be an integral part of deliberative activities for normative reasons (but provide little detail as to how this would happen). Others reveal an instrumental desire to see particular hESC research policies advanced and, so, express ostensibly ‘process-based’ criteria about public inputs or experts in instrumental, ‘outcome-based’ ways. Though more will be said in later chapters about these motivations, analysis of stakeholder views in light of discussions about normative, instrumental and substantive motivations behind the appraisal of good governance further enhances our ability to illuminate how perspectives on good governance are constituted.

The analysis has also shown the ability of the elicitation methodology to uncover otherwise hidden framing assumptions and judgements about the options themselves. If we recall the option performance rankings under all issues for US and UK stakeholders, there was a fair degree of similarity in the overall structures in these rankings. Superficially, this might encourage a conclusion that the underlying framings are also

convergent. However, analysis of these framings has shown that similarities in the aggregate performance rankings actually conceal important differences between performance patterns under specific criteria. Analysis of these differences illuminates significant variations in the framings, assumptions and socio-political values that constitute perspectives on good governance. The next chapter will build on this observation, by exploring the differences in perspectives across different groups of stakeholders. Thus, it will provide a different ‘cut’ of perspectives and allow us to compare across inter- as well as intra-national levels.

7. Stakeholder perspectives on good governance: comparative analysis of multiple stakeholder groups

7.1 Introduction

7.1.1 Overview

The previous chapter discussed the findings from the analysis of stakeholder perspectives on good governance in UK and US settings. It was argued that patterns and distinctions can be identified in the ways perspectives are constituted. This is true both of the empirical data, as elicited using MCM, and in the analysis of the formal policy literature. In themselves, these findings may hold implications for wider theory-building and policy analysis of the governance of science and technology. However, a robust discussion of these implications cannot be undertaken until a full analysis is completed. Specifically, addressing the research question requires not only an understanding of how stakeholder perspectives differ across national settings, but also how they might differ across and within *different* stakeholder groups. Building on the main hypotheses of this thesis, we suggest:

- *it may be possible to discern discrete perspectives amongst the different types of stakeholder groups extant in each national setting;*
- *amongst these discrete perspectives, patterns, regularities and systematic differences can be identified and analysed;*
- *distinctions and patterns within and across perspectives on good governance among different stakeholder groups can be compared in potentially illuminating ways; and*
- *these patterns may have implications both for wider theory-building, as well as allowing for further explanation of technological and socio-political factors in decision-making under varying conditions of risk and uncertainty.*

This chapter will address these inter-related hypotheses and explore their implications for the thesis. As with the previous chapter, the perspectives will be discussed within the framework that has structured the empirical discussions thus far concerning distinct ‘themes’ of good governance. This allows us to continue testing the robustness of these themes as well as ensuring a consistent, structured and systematic probing of the empirical material.

The remainder of this introductory section will discuss the findings of the MCM interviews in a comparative light across multiple stakeholder perspectives, as opposed

to the two national ones discussed previously. Section 7.1.2 will describe the stakeholder groups as approached initially for the purpose of designing the research¹⁰¹ and as resolved in later analysis of associated perspectives. The discussion in Section 7.1.3 will move to the final ranking patterns for the contrasting governance options as obtained for each of the initially-identified stakeholder groups. This analysis will be used to identify points of convergence and divergence, emerging patterns and areas of analytical interest. The remaining sections will explore the empirical findings in further detail. Due to the sheer volume of data collected, not every theme can be explored at the same level of resolution. Where a particular analysis is not presented or discussed, reference is made to supporting Annexes.

7.1.2 Analysis of general results and issues

In the methodology chapter we discuss how the initial grouping of stakeholders was conducted for the purposes of establishing the interview cohort. We also point out how within an MCM analysis one is not necessarily constrained to analysing the data along such lines. In an MCM analysis, there are multiple ways to ‘cut’ the empirical data—for example, by national setting or professional affiliation. Each ‘cut’ is determined according to the hypotheses being tested and so each test must be reflexive not only about the conclusions that are reached, but also about the initial categories with which the analysis begins.

The five main perspectives summarised in Table 7.1 and used throughout the analysis in this chapter were settled upon as the result of testing many such ‘cuts’ of stakeholder perspectives. This is pointed out simply to be explicit that these were both the starting point for the analysis as well as the final end point. Therefore, it is not our contention that these groupings of socio-political viewpoints are in some way definitive, merely that they emerged as the most suitable for the analysis here.

¹⁰¹ See the discussion on p. 68 in Chapter 4.

Table 7.1: Summary of initially-defined perspectives

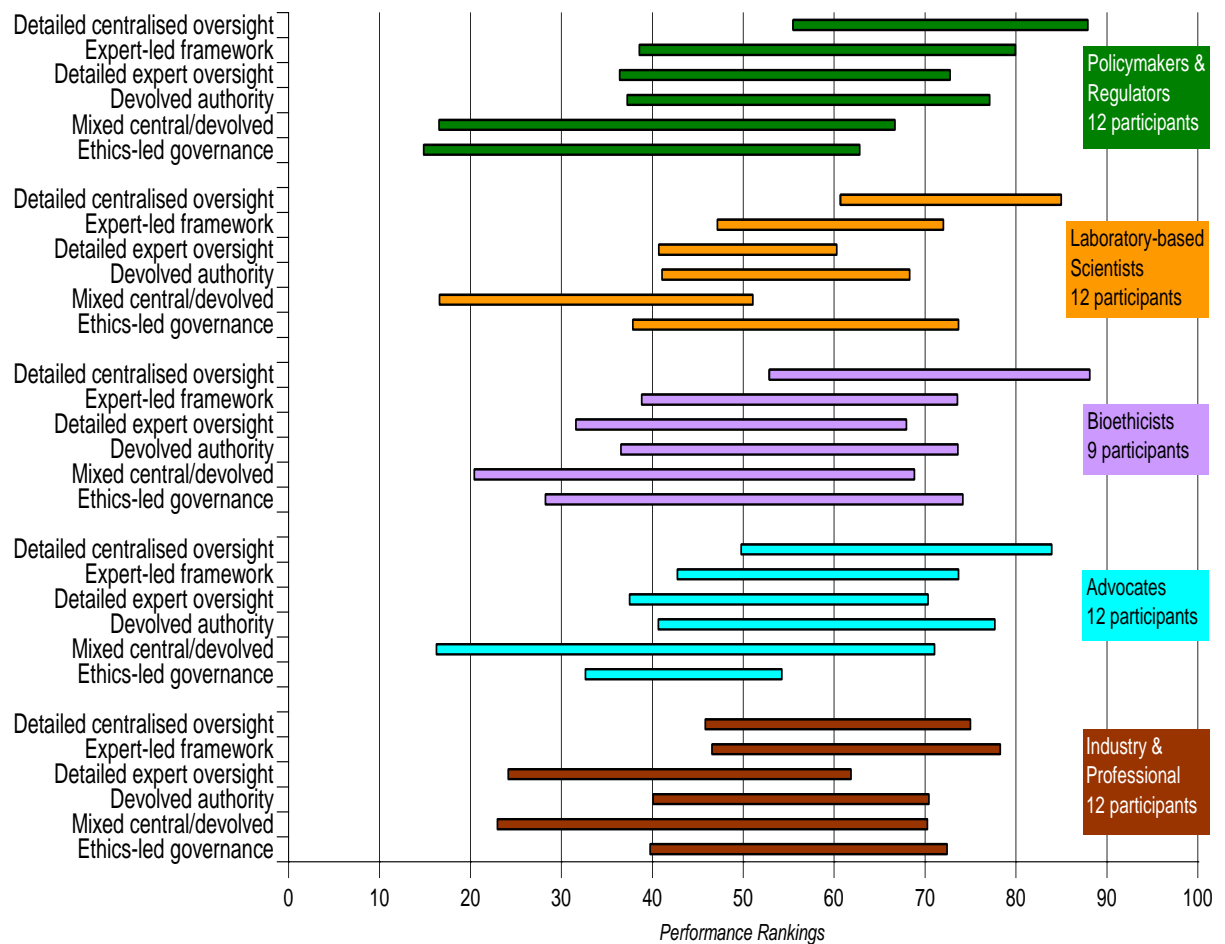
Perspective Name	Total number of participants	Total number of criteria defined	Perspective definition
Advocates	12 participants (6 US & 6 UK)	64 individual criteria	This perspective is broadly inclusive of advocacy groups working to advance a particular policy position related to hESC research. It includes participants in <i>patient advocacy groups</i> working on behalf of patients afflicted with a variety of medical conditions and <i>policy advocacy groups</i> , where the organisation takes a specific policy stance regarding hESC research in line with the members they represent. Further divisions are evident between those advocates who are broadly <i>supportive</i> of hESC research and associated governance structures, and those who are broadly <i>opposed</i> to them.
Bioethicists	9 participants (5 US & 4 UK)	50 individual criteria	This perspective includes individuals who are working as bioethicists in a variety of capacities, be they academic, medical, advisory or policy-based. Importantly, all individuals in this perspective have some formal training in the practice and intellectual thought associated with bioethics as a 'discipline', through either academic or professional training.
Industry and Professional	12 participants (6 US & 6 UK)	65 individual criteria	This perspective is comprised of individuals who are either <i>industry executives</i> working in companies involved in the commercialisation of stem cell related technologies or therapies, or executives representing a <i>professional body</i> that describes itself as acting on behalf of a commercial or industrial sector that has a vested interest in stem cell research.
Policy-makers and Regulators	12 participants (8 US & 4 UK)	65 individual criteria	Includes policy-makers and regulators at state and national levels, in addition to science policy specialists in national funding or policy advisory bodies. It also includes those who are policy and regulatory specialists by virtue of their position as expert advisors on national or state policy advisory commissions or statutory bodies.
Scientists (Labs)	12 participants (5 US & 7 UK)	66 individual criteria	This group includes established and new researchers in the field of stem cell science, reproductive technologies or biomedicine (but with a particular expertise in stem cell research). It also includes scientists with a variety of research trajectories, including basic research, applied and clinical. All participants in this group work in research laboratories and the majority of their time is spent actively engaged in research.

A few points from the summary table are worth noting briefly. First, the distribution of the 57 participants across the five perspectives is fairly even. Second, and relatedly, the balance between UK and US participants in each group is relatively even

(except for policy-makers and regulators¹⁰²). Third, all the groups defined proportionally similar numbers of criteria.¹⁰³ All of these factors contribute to the decision to use this initial grouping of stakeholders as the foundational set of socio-political viewpoints for the remaining analysis. However, as we will see, some variations within each group did emerge as relevant during the analysis and these are reviewed in the analysis below.

Figure 7.1 shows the option rankings under each of the perspectives identified above. We can see that there are systematic similarities and differences in option performance across all perspectives. These are reviewed below.

Figure 7.1: Rankings under initial stakeholder perspectives¹⁰⁴



¹⁰² As discussed on p. 68-69, this is due to the need to represent a range of state-based perspectives in the US. The eight individuals represent a mix of state and national policy-makers and regulators.

¹⁰³ This in itself is not surprising as each individual was encouraged to keep their criteria within a certain range to prevent the process from either becoming unwieldy at one extreme (from too many criteria being defined) or ineffective at distinguishing amongst the options at the other (if too few criteria were defined). Nevertheless, the relatively balanced categories allow us to be more confident in the initial constituting of categories as an even starting point for analysis.

¹⁰⁴ As explained in the previous chapter and the methodology chapter, the extreme lower and upper ends of the ranking ranges for each option, are represented as the *means* respectively of the pessimistic (minimum) and optimistic (maximum) rankings obtained in each case.

Analysis of the rankings shown above reveals a degree of similarity in certain features of the ordinal pattern across most of the perspectives, echoing the findings made under UK and US rankings in the previous chapter.¹⁰⁵ As with all such MCM ranks, these patterns are qualified by significant ranges of uncertainty within individual viewpoints and ambiguity across perspectives – as displayed by the relatively extensive lengths and overlaps in the ranking intervals. But the patterns are nonetheless consistent. These include: *i*) the detailed centralised oversight option is consistently assigned a relatively high performance, *ii*) the expert-led framework closely follows the high performance of the detailed centralised oversight option, *iii*) the mixed central/devolved option is repeatedly portrayed as among the lowest performing, and *iv*) there is more variation in ranking patterns for the options with significant ‘devolved’ components across the stakeholder groups.

Though these patterns, especially the first three points, mirror those observed in the previous chapter, what is different here is the extent to which potentially significant variations are apparent within the ordinal patterns across the perspectives. For example, the extent to which the detailed centralised oversight option is the highest ranking option under optimistic scores varies, revealing significant differences in the assumptions made about good governance under different perspectives. Among bioethicists and laboratory-based scientists, the detailed centralised oversight option has the highest ranking by a factor of almost 50% of the full interval of the ranking range.¹⁰⁶ This seems to indicate a rather strong preference for this option amongst these groups. For other groups, however, the relative extent to which this option ranks higher than others at the optimistic end of the scale is not as large; moreover, for the industry and professional group it is not the highest at all. This suggests a closer relationship between the contingencies, nuances and (perhaps more) veiled assumptions which affect option performance under these perspectives.

Just as the detailed centralised oversight option has a consistently high ranking across all the perspectives, so the mixed central/devolved option displays both a relatively low ranking and a consistently high expression of uncertainty and ambiguity

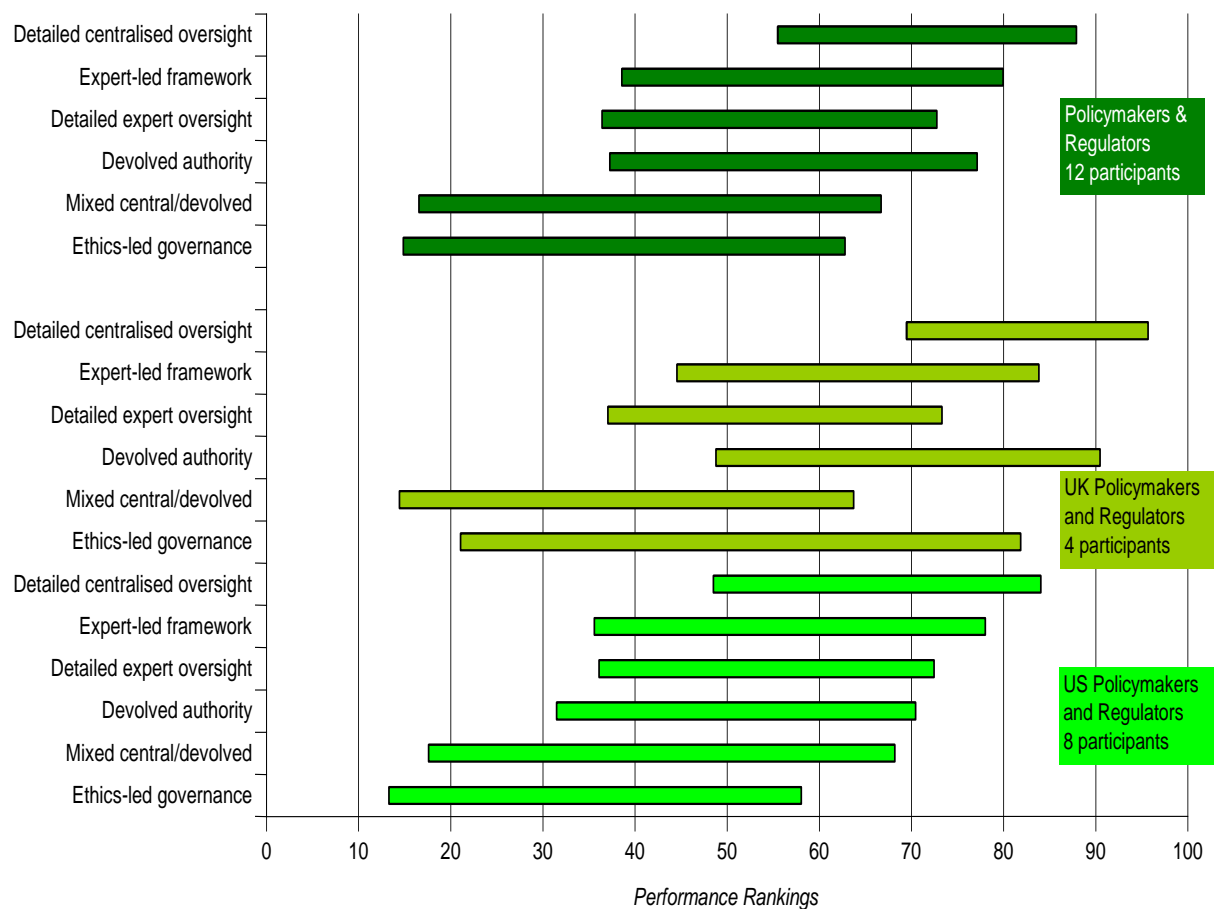
¹⁰⁵ See the discussions in Chapter 6, in particular p. 132-135

¹⁰⁶ For example, for bioethicists the interval for the detailed centralised oversight option is approximately 35 base points long and the next highest performance ranking is 14 base points lower than the highest point rank of the detailed centralised oversight option. Similarly, for laboratory-based scientists, the length of the rank bar for the detailed centralised oversight option is 24 and the next highest performance ranking option is 11 base points lower.

across all the perspectives. Considering the similar findings in the previous chapter, we might now be able to identify something inherent to this option, of a kind that transcends stakeholder perspectives, rendering it more susceptible to uncertainty and ambiguity over its potential to fulfil general notions of good governance.

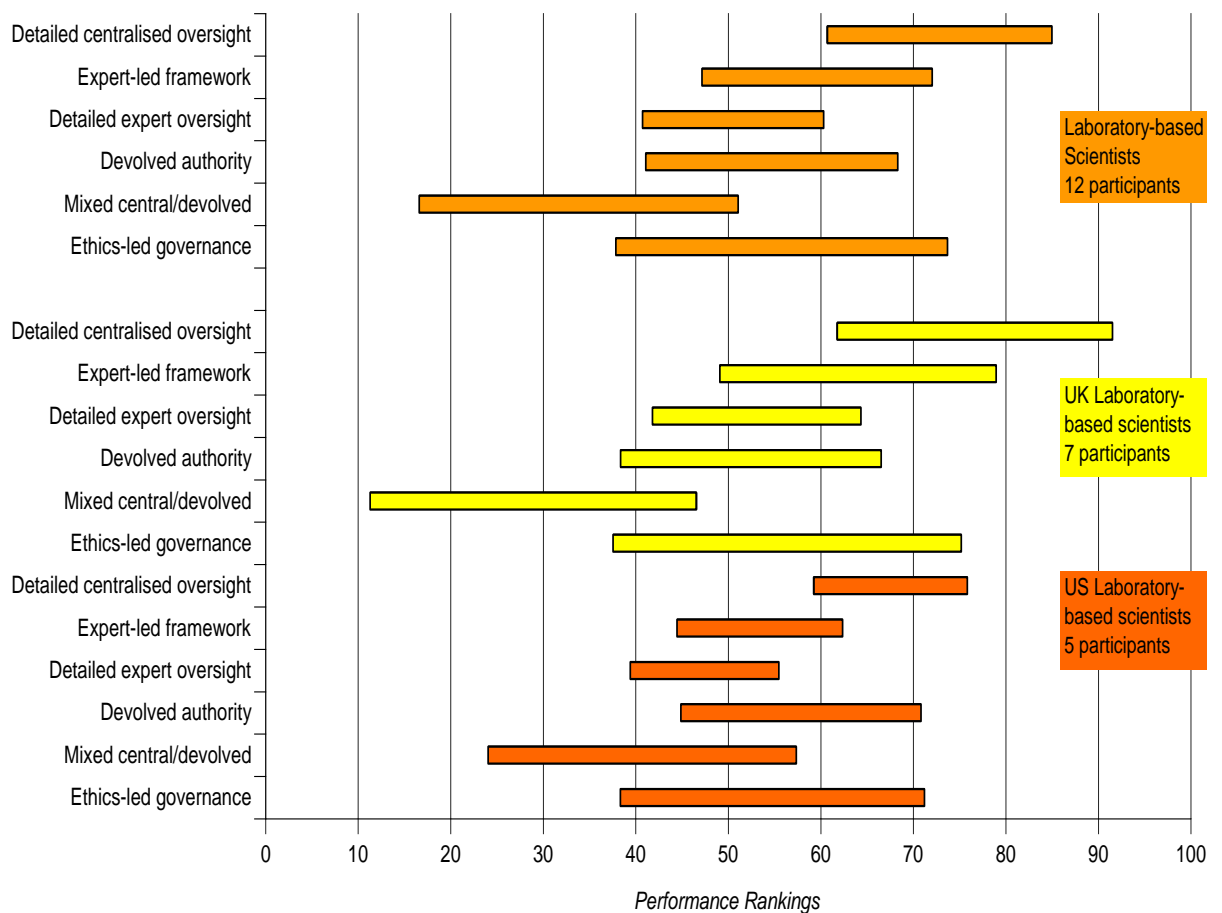
If we now turn our attention to each perspective, there are further features of the ranking patterns worth pointing out. These are apparent not only as displayed above, but also at more discrete *intra*-perspective levels. For each of the next five figures, the stakeholder perspectives resolved above will be taken as a starting point upon which further resolution of additional perspectives might be found. It should be noted that the following discussion purposely takes a systematic approach to discussing option performance for each stakeholder group. Due to the breadth of the findings, we feel it is important to give the reader such a structured overview of the aggregate ranking patterns and analytical issues that these suggest. The analysis in the remainder of the chapter is not always so systematic, instead emphasising important analytical ‘storylines’ and pointing the reader to corroborative details in relevant annexes.

Figure 7.2: Rankings under UK and US policy-maker and regulator perspectives



We can see in Figure 7.2 that there is a clear difference in the pattern of performance rankings across the two perspectives, with the UK group displaying greater distinctions between option performance than the US group. The highest ranking option under UK policy-maker and regulator views is the detailed centralised oversight option. Even under the most pessimistic scores for this option, it still performs better than the most optimistic scores given to the worst performing option, mixed central/devolved. This feature is notable. When the ‘worst of the best’ and the ‘best of the worst’ fail to overlap, it offers a clear indication that one option is more favourable under all sets of conditions as specified by the participants within that group. We do not see, however, a corresponding picture for US views in this stakeholder group. The greater overlap between ranking patterns suggests there may be more points of convergence in the circumstances under which different options are seen to perform well. This will be an area for further analysis and exploration in the following sections.

Figure 7.3: Rankings under UK and US laboratory scientist perspectives



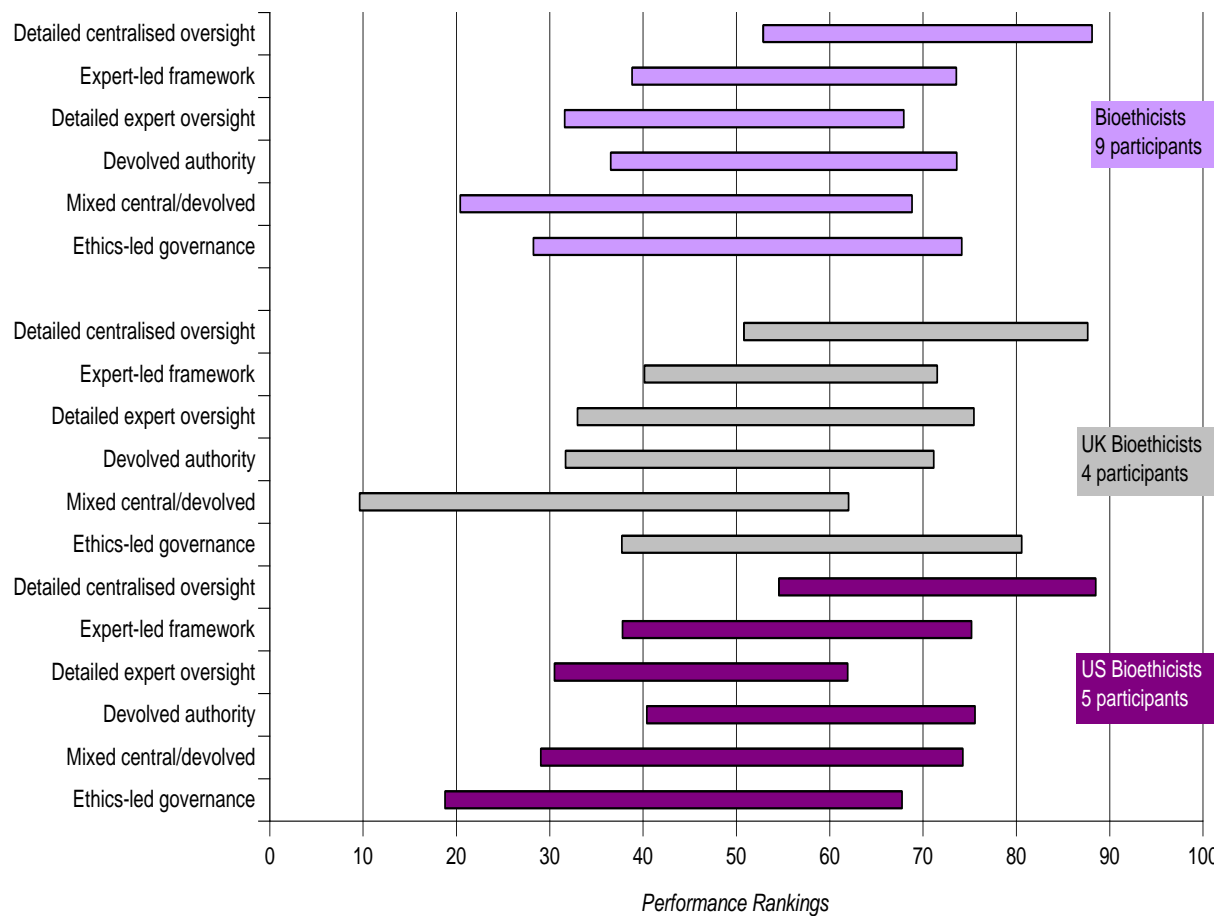
In Figure 7.3, all perspectives display a minimal degree of overlap between options. There is a clear distinction in each case between the highest performing option,

detailed centralised oversight, and two of the lowest performing options, the mixed central/devolved and detailed expert oversight. Again, this situation where the ‘best of the worst’ and ‘worst of the best’ display little or no overlap gives a clear indication of preference for a particular type of option under all conditions. This is of particular interest because these highest and lowest performing options display opposing degrees of each of the three dimensions of governance employed in the option definitions.¹⁰⁷ The highest performing option, detailed centralised oversight, has detailed regulations, centralised oversight and a mix of technocratic and democratic deliberations. The lowest performing option, mixed central/devolved, has a greater emphasis on decentralised oversight and a mix of technocratic and democratic deliberative mechanisms. The option performance patterns, then, seem to suggest that for the scientists interviewed it is not just singular characterisations of governance, such as ‘central oversight’ or ‘detailed regulations’, that affect option performance, but rather the ways in which the dimensions are seen to interact within a given framework.

Another feature of these ranking patterns is the difference in expressions of uncertainty and ambiguity across the two national groupings of scientists. While accompanying charts displaying the relative degrees of uncertainty are provided in Annex J, for present purposes it is sufficient to point out that UK scientists seem not only to express greater uncertainty in the option assessments than US scientists (with an average interval uncertainty range across all options of 6.2 base points for UK scientists and 4 base points for US scientists), but detailed analysis shows the UK group as a whole displays greater ambiguity than the US group.¹⁰⁸ In other words, there is a greater tendency for more disagreement about option performance amongst UK scientists than US scientists. It is this, alongside the greater uncertainty, that determines the wider ranges in rankings seen above.

¹⁰⁷ From the discussion in earlier chapters (p. 54-56 and p. 70) these three dimensions of governance are: i) decentralised vs. centralised institutional oversight, ii) prescriptive regulations vs. general frameworks of policy, iii) technocratic deliberations vs. democratic deliberations about policy decisions.

¹⁰⁸ As we noted above, ambiguity can only be determined at the level of rankings under criteria groups, so part of this conclusion is based on analysis that will be provided in sections below.

Figure 7.4: Rankings under UK and US bioethicist perspectives

The ranking patterns for bioethicists as seen in Figure 7.4 above are similar in some respects to those of policy-makers and regulators, with the exception of the ethics-led governance option. This raises the question of where and how the evaluative criteria and option assessments converge and diverge between the two perspectives. This type of analysis might be done with an eye towards the literature reviewed earlier in this thesis about the rise of a new form of expertise in policy-making – that of bioethicists. Further comments in this regard will be made throughout this chapter and the next.

In addition to this inter-perspective observation, we see some divergence in the ranking patterns obtained by UK and US bioethicists. This divergence is interesting because it only happens for three of the options, the detailed expert oversight, the mixed central/devolved and the ethics-led governance. The other three options all retain the same relative patterns across the two national groups. This seems to suggest that under this perspective there may be something more relatively ‘stable’ about the latter group of options than the former group, leading them to be evaluated in a similar way.

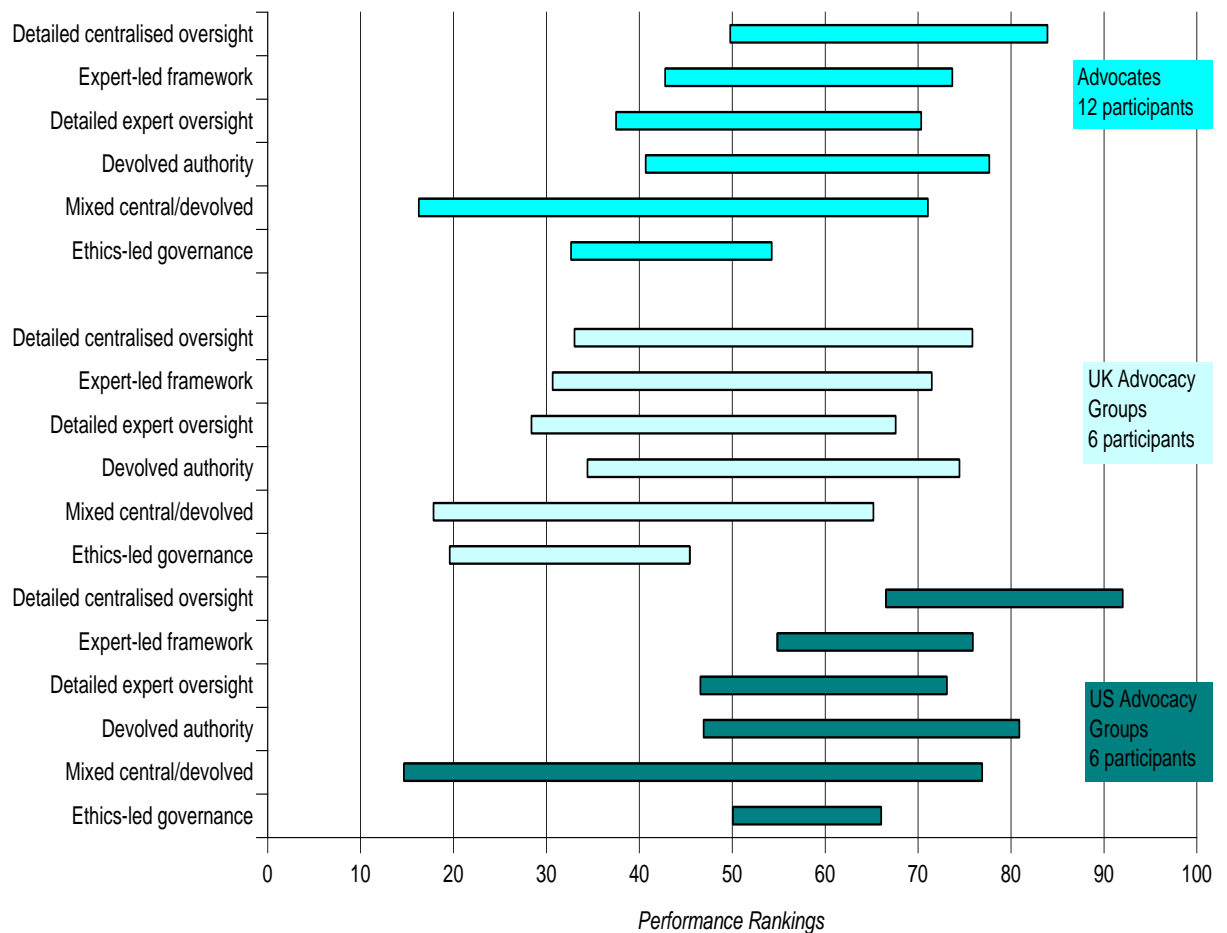
Figure 7.5: Rankings under UK and US advocacy group perspectives

Figure 7.5 displays the rankings for the different national advocacy group perspectives. It was noted earlier that there was a great deal of uncertainty and ambiguity expressed in the mixed central/devolved option under this perspective. We can see looking at the two national groupings that much of this extended range is due to the US advocacy group. In fact, the uncertainty and ambiguity expressed in this option ranking under US advocacy perspectives is (at 62 base points), one of the greatest out of all perspectives.¹⁰⁹

We might recall that the mixed central/devolved option was derived (and presented) as analogous to the current US system of governance and the detailed centralised oversight option as analogous to the UK governance system. It is interesting to note, then, that for the UK advocacy stakeholder group, we also see that the option analogous to the stakeholder group's own existing national governance system displays a relatively high degree of uncertainty and ambiguity. Moreover, this is the first time in the analysis presented thus far where this particular option displays such high

¹⁰⁹ Uncertainty at the perspective level for these rankings is shown in Annex J. Ambiguity can only be determined under individual issues, and hence is explored later in this chapter.

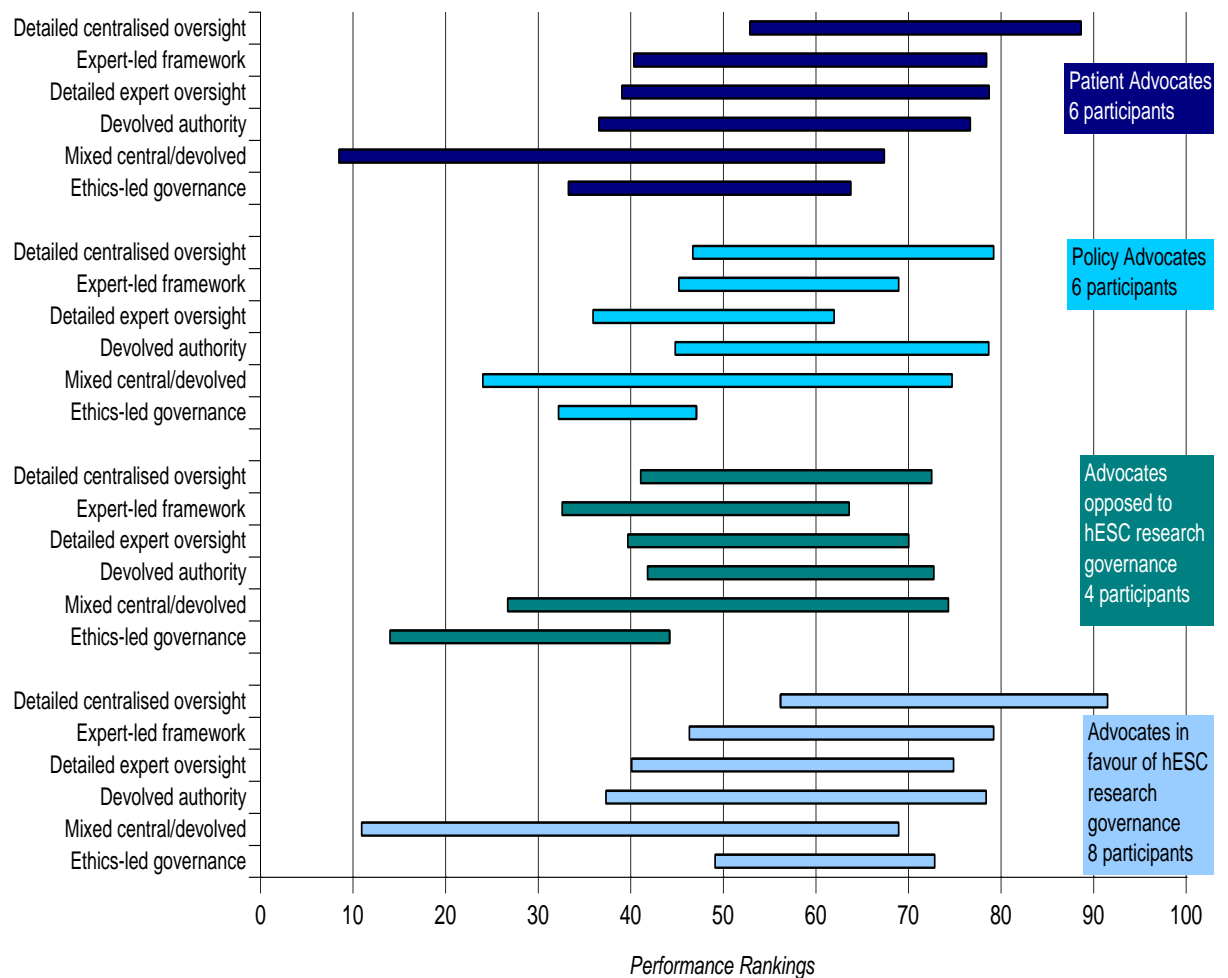
uncertainty and ambiguity – or such low performance relative to other options. Based on these findings for both UK and US instances of this stakeholder perspective, we might hypothesise that there is something inherent to the particular framings and socio-political views of advocates which lead them to express more uncertainty and ambiguity about governance systems with which they are most familiar.¹¹⁰ It may be the case that when the focus turns (explicitly) to such systems, advocates are more likely to be critically aware of the contingencies affecting both negative and positive outcomes and processes of good governance.¹¹¹

The divergent normative policy positions advocated by different stakeholder groups may also be expected to affect option performance. In order to explore this, we look to the rankings obtained by subsets of these stakeholder groups concerned with (i) patient advocacy, (ii) policy advocacy, and (iii) support of and (iv) opposition to, hESC research. This breakdown is shown in Figure 7.6 below. Across all these cases, we can see there are marked differences in the ranking patterns, suggesting that resolvable distinctions do exist in perspectives on ‘good’ governance within these groups.

¹¹⁰ A separate exploration of uncertainty in relation to this point can be found in Annex J.

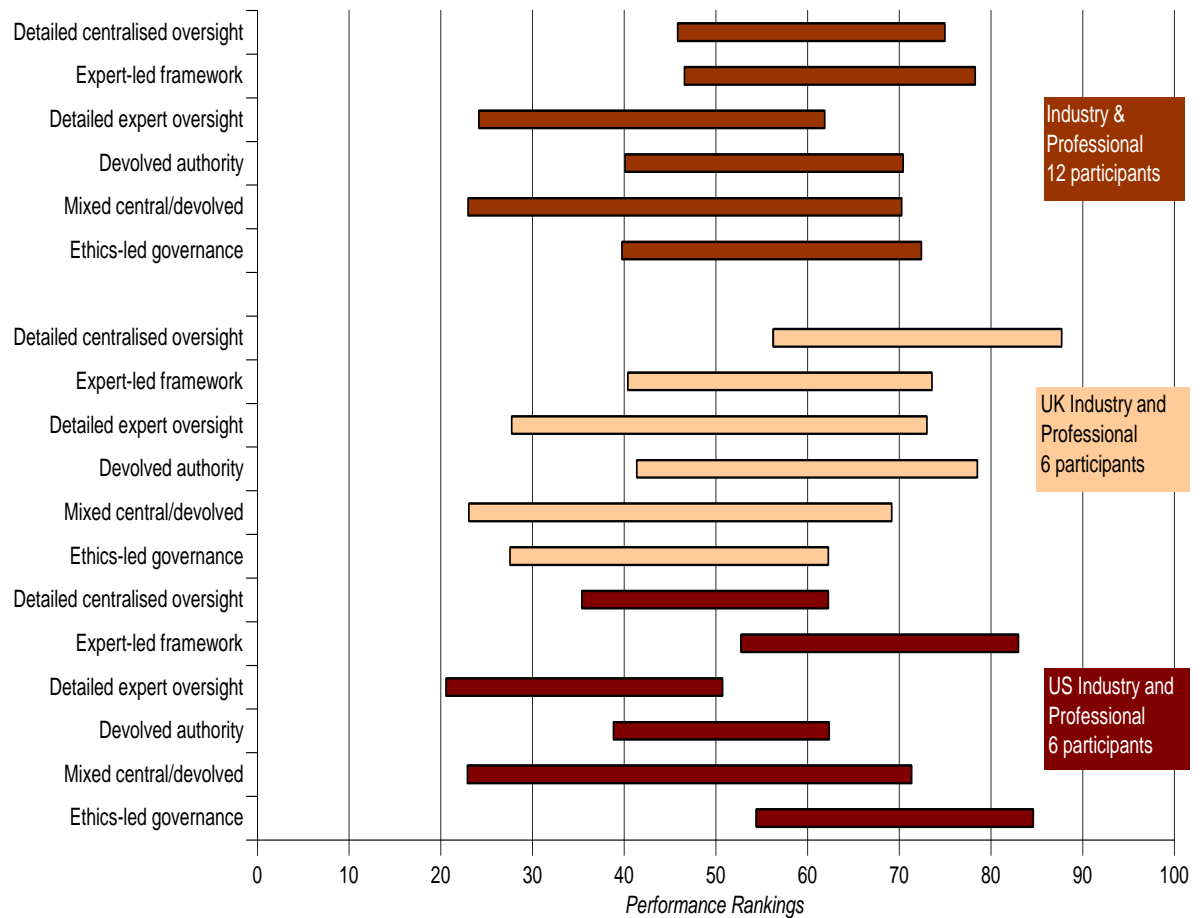
¹¹¹ This finding cannot be confidently made unless compared with other possible cases. It is only pointed out here to raise the possibility, not to claim it as a definitive statement.

Figure 7.6: Rankings under patient, policy, opposition and supportive advocacy perspectives



Though the number of participants in the group of advocates opposed to hESC research governance is smaller than those in favour of it, we can still explore the ranking patterns for systematic differences. Indeed, as with the overall stakeholder group as a whole, some of the most notable patterns are found in the differences in the evaluation of the detailed centralised oversight, mixed central/devolved and ethics-led governance options. In addition, although there are more distinct differences in the patterns between those opposed to or in favour of hESC research, there are also some similarities worth exploring, such as the consistently higher ranking of the devolved authority and detailed centralised oversight options in comparison with the others. All of this can be taken to suggest that analytic attention might be paid to these areas throughout the chapter.

Figure 7.7: Rankings under UK and US industry and professional executive perspectives



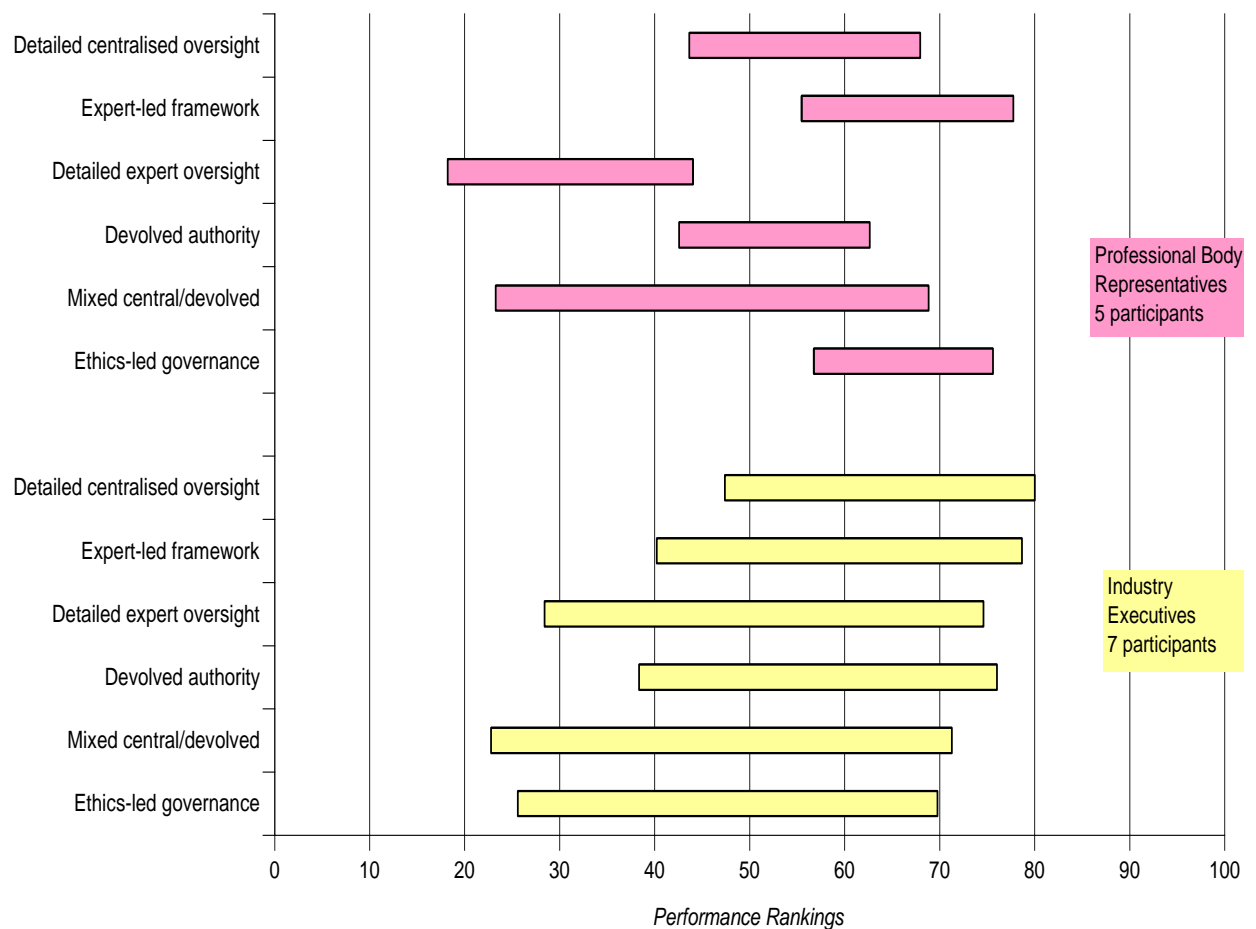
Finally, the last perspective to be presented is that of industry and professional executives. Figure 7.7 shows a notably different ranking pattern for this stakeholder group by comparison with the perspectives already discussed. As mentioned previously, this is the only stakeholder group where the detailed centralised oversight option does not have the highest performance ranking. Such differences in the ordinal pattern compared with other groups suggests the perspectives on good governance held by industry and professional executives might be constituted in distinct ways, or at the very least are affected by a more significantly different set of framing assumptions.

The nation-specific rankings for this stakeholder group also reveal different patterns, most notable for US industry and professional executives. Thus, not only are the patterns for this perspective different to others at the *inter-perspective* level, they are also more divergent *within* the perspective, nationally. Though this latter feature has been seen throughout the rankings presented thus far, it is perhaps most marked for this group. In particular, the fact that US-based industry and professional executives express a preference for the two options that highlight both scientific autonomy and the role of

expert-based decision-making, indicates a more ‘free market’ perspective might be held by US participants in this group.

Given the remarkable nature of the different ranking patterns yielded within this perspective, it is worth considering other cuts within this group. As Figure 7.8 shows, we also find markedly different patterns across the views of executives of professional body organisations versus those in industry. In fact, the relatively high degree of overlap in the rankings of industry executives perhaps indicates a greater sensitivity to the contingencies that affect option performance; while in the professional executives’ perspective clearer distinctions are made. Or, looked at another way, for industry executives it seems there is little distinction made between the options at the optimistic end, whereas greater distinctions come when considering the pessimistic circumstances which may affect option performance. This may be indicative of a view which holds that market conditions are variable and, given a positive governance outlook, any framework could perform well.

Figure 7.8: Rankings under industry and professional executive perspectives



Though much of the preceding analysis has focussed on differences within ranking patterns, we should not lose sight of the similarities across option rankings, such as the high performance ranking of the detailed centralised oversight option. This suggests that there may be important features of the options themselves which are consistent across multiple socio-political viewpoints and perspectives on good governance. Attention to both similarities and differences in ranking patterns will allow us more fully to understand the normative implications for decision-making in this contested area of biomedical science.

Having explored the performance rankings for the individual stakeholder groups, we can appreciate the complexity and diversity of analysis that must be grappled with. In order to better guide the reader through this, Table 7.2 summarises the contrasting perspectives that will be discussed in the remaining pages of this chapter for each of the initial stakeholder groups. Each perspective is discussed according to the themes of good governance resolved in earlier chapters and the basis for the identified perspectives was made in a similar way to that described in the previous chapter.¹¹² Those perspectives indicated with a darker shading show particularly strong systematic patterns or areas of analytical interest. Thus, these analytical ‘storylines’ will be the main focus of the discussion in this chapter.¹¹³

¹¹² See the discussion in Chapter 6, p. 135-136.

¹¹³ Supporting or tangential information in less prominent storylines is presented in Annex J.

Table 7.2: Contrasting perspectives on themes of good governance¹¹⁴

		Policy-makers & Regulators	Scientists (Laboratory)	Bioethicists	Advocates	Industry & Professional
Advances scientific & technological outcomes & addresses related issues in hESC research	Qualities of scientific outcomes	Emphasis on 'good' science	Basic science	Beneficent science	Public interest science	Innovative science
	Processes & mechanisms for research support	Establish proportionate regulation OR Ensure harmonised policies (UK/US split)	Provide leadership & guidance	Varies with participant background	Achieve outcomes through centralised processes	Ensure freedom to operate
Establishes appropriate Institutions & instruments for hESC research	Qualities of deliberative activities: publics	Ensure public trust	Gain public support	Pragmatic pluralism	Promote open engagement	Gain public support
	Qualities of deliberative activities: expertise	<i>Process-based: Balanced views</i>	Composition and Process-based	<i>Purpose-based: Informed decisions</i>	Various: representative and transparent	<i>Composition-based: 'Who' is the expert?</i>
Identifiable social & cultural bases of good governance	Bases of trust and legitimacy	Institutional	Educational	Pluralism	Eye of the beholder	Professional representation

Shading Key:

	<i>Indicates a particularly strong signal from the empirical data and emphasis is placed on these areas in the text.</i>
	<i>Indicates a clear signal from the empirical data, but findings are not always central to argument.</i>
	<i>Indicates some individual points from the analysis were of interest, but overall the findings are not central to the argument and, moreover, there was not sufficiently clear signal to merit further analysis.</i>

This table is merely meant to provide an 'overview' for the reader and will not be described in any additional detail here. Full discussion under each theme is taken up in the text below and we will move directly to that discussion now. The next section, 7.2, discusses stakeholder perspectives under the theme 'advancing scientific and technological trajectories'. The analysis will explore the qualities of scientific outcomes that are described by stakeholders and the processes of research support that facilitate their achievement.

¹¹⁴ The omitted theme, 'encourages ethical and moral awareness for hESC research' and sub-theme, 'characterising policy approaches', are analysed and discussed in Chapter 8.

7.2 Advancing scientific and technological outcomes

7.2.1 Overview

In discussion of this theme in the previous chapter, the perspectives of UK and US stakeholders were analysed for overarching patterns in the way that qualities of scientific outcomes were characterised and the corresponding processes of research support articulated. The focus here remains the same, but the unit of analysis shifts to the five main stakeholder groups. As before, the issue is first defined for the purposes of making explicit the step in the analysis where individual criteria are grouped because they share similar features.

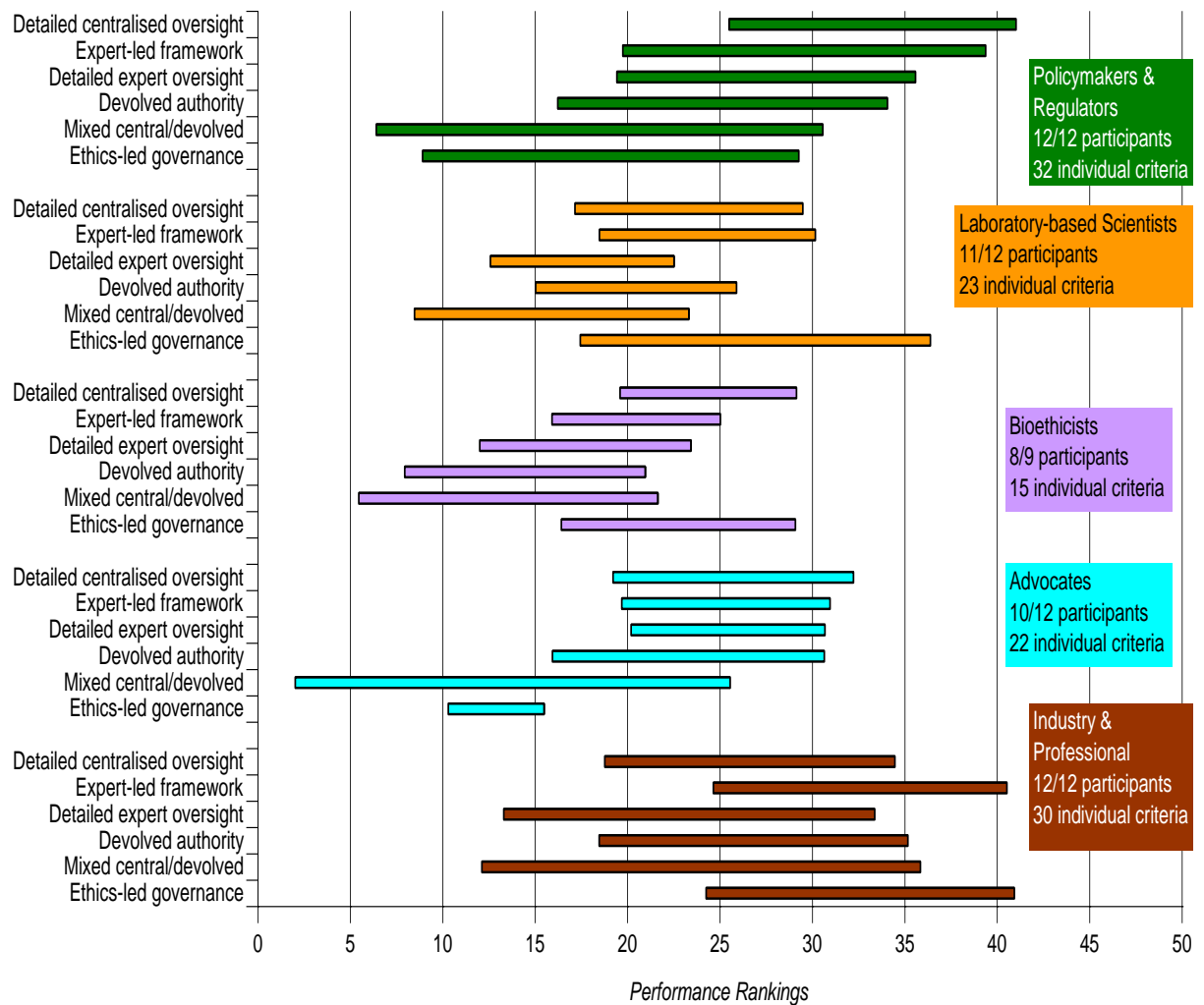
***Advancing the science:** Criteria in this issue are distinctive in their concern with fostering and advancing the science of hESC research itself. Often expressed in an instrumental way, the criteria are concerned with the need for the governance framework to facilitate, support and actively advance the research, technological and therapeutic trajectories of human embryonic stem cell research.*

The criteria that comprise this issue reveal framings about the nature of the science, the directions in which it might advance and the qualities of the outcomes it might achieve. The criteria also reveal perceptions about what is needed, in ‘good’ governance terms, to facilitate particular outcomes. These needs might include features of financial, social or policy support. Evaluation of these factors at the individual stakeholder group level will further enrich our understanding of how perspectives on good governance are constituted.

7.2.2 Scientific outcomes and research support

The analysis presented in this section will look at the framings of hESC research and desired outcomes, be they research-, therapeutic- or commercially-oriented and associated processes of research support. This issue is the most frequently mentioned amongst all of those analysed and so the findings below are of central importance. We will begin by looking at the rankings obtained by the five initial stakeholder groups under the issue ‘advancing the science’, before moving on to the detailed analysis.

Figure 7.9: Rankings under stakeholder perspectives for ‘advancing the science’ criteria¹¹⁵



We can immediately see from this chart that there are divergent ranking patterns across the perspectives. The strongest pattern seems to be that of systematic divergence in the ordinal option rankings. That is, no one option has the highest performance ranking under optimistic scores amongst a majority of the stakeholder groups. Moreover, different ranking patterns exist in each group. The notable exception to this is the performance rankings seen for the stakeholder groups ‘bioethicists’ and ‘policy makers and regulators’ (with the exception of the ethics-led governance option). This finding suggests an intriguing synergy between these two groups which will be explored more fully in the following chapter.

¹¹⁵ As in the previous chapter, when ranking patterns are presented under certain criteria groups (issues), only a subset of all criteria may fall within any given grouping. Similarly, not all participants in the stakeholder group (perspective) presented may have defined a criterion within the issue, while some may have defined several criteria within the issue. Thus, each box in the figure displays information regarding the number of participants defining at least one criterion within the issue (e.g., ‘x/x participants’) and how many criteria, in total, comprise the issue within that perspective (e.g., ‘x individual criteria’).

Overall, the tendency towards divergence rather than convergence in ranking patterns suggests that there may be relevant distinctions between perspectives in their characterisations of salient issues. These may be found both in relation to the framings of hESC research outcomes as well as the requisite processes of research support. It is to these distinctions that we now direct our attention.

Looking first to the way in which the criteria are defined and option assessments made within the group of policy-makers and regulators,¹¹⁶ participants tend to speak about scientific outcomes in terms that emphasise support for, alternatively, ‘good’, ‘meritorious’ or ‘the best’ science. Although some criteria specifically mention therapeutic developments as a goal, most were concerned simply with ensuring that high quality science is supported. As articulated in a criterion defined by one US-based policy-maker,

meritorious science is science that respected experts consider to be quality science... In terms of supporting meritorious science, implicit in that is you are not creating unnecessary barriers to the performance of the science itself and collaborations between scientists... Doesn't mean you create no barriers, but they shouldn't be so high they impede the progress of the science (US policy-maker 8, #C237).

Within this single criterion we find a related emphasis both on the framing of hESC research outcomes – in terms of good or ‘meritorious’ science being pursued – as well as the processes which should facilitate this – not creating ‘unnecessary barriers’. It is interesting that many participants asserted similar views that the scientific priority should be quality science, not specific biomedical applications. As argued by one US policy-maker, in order to “foster scientific breakthroughs and disease therapy translation” it is necessary to think more about how to support research and less about specific outcomes: “[It’s about] funding the best science rather than going the disease-specific route” (US policy-maker 6, #C266). Thus, outcomes of hESC research are framed in broadly scientific terms, as opposed to therapeutic ones, by policy-makers and regulators in this stakeholder group.

Despite this similarity, there are differences in how UK and US participants in this group characterise their criteria. Proportionally,¹¹⁷ more of the criteria defined by UK members of this group relate to the *processes* of supporting hESC research, not the qualities of *outcomes*. Conversely, almost half of the criteria defined by US members

¹¹⁶ The ranking chart comparing UK and US policy-makers and regulators can be found in Annex J.

¹¹⁷ For UK policy-makers and regulators, seven out of ten criteria in this issue are about processes of supporting advances in hESC research, while for US policy-makers and regulators 13 out of 22 criteria of this type were defined, leaving just under 50% discussing the quality of scientific outcomes.

focus on the qualities of hESC research outcomes, specifically those where ‘good’ science results. This might be interpreted as being reflective of the greater political opposition to hESC research in the US. US policy-makers and regulators may feel more acute pressures to justify hESC research by emphasising its purposes, or intended outcomes. Conversely, in the UK ‘the purpose of the research’ is inscribed in legislation (UK policy-maker 2, #C137), and so there might be less of a pressure on UK policy-makers to justify hESC research in the first place. Thus, they may feel more able to discuss how to facilitate scientific advances of any and all kinds. Unsurprisingly, then, we seem to see a link between the current policy context in each country and the associated policy-maker perspectives on good governance.

We also find national differences in the ways in which processes of research support were characterised by UK and US policy-makers and regulators. The following quotes are illustrative of the ways each national group made this point.

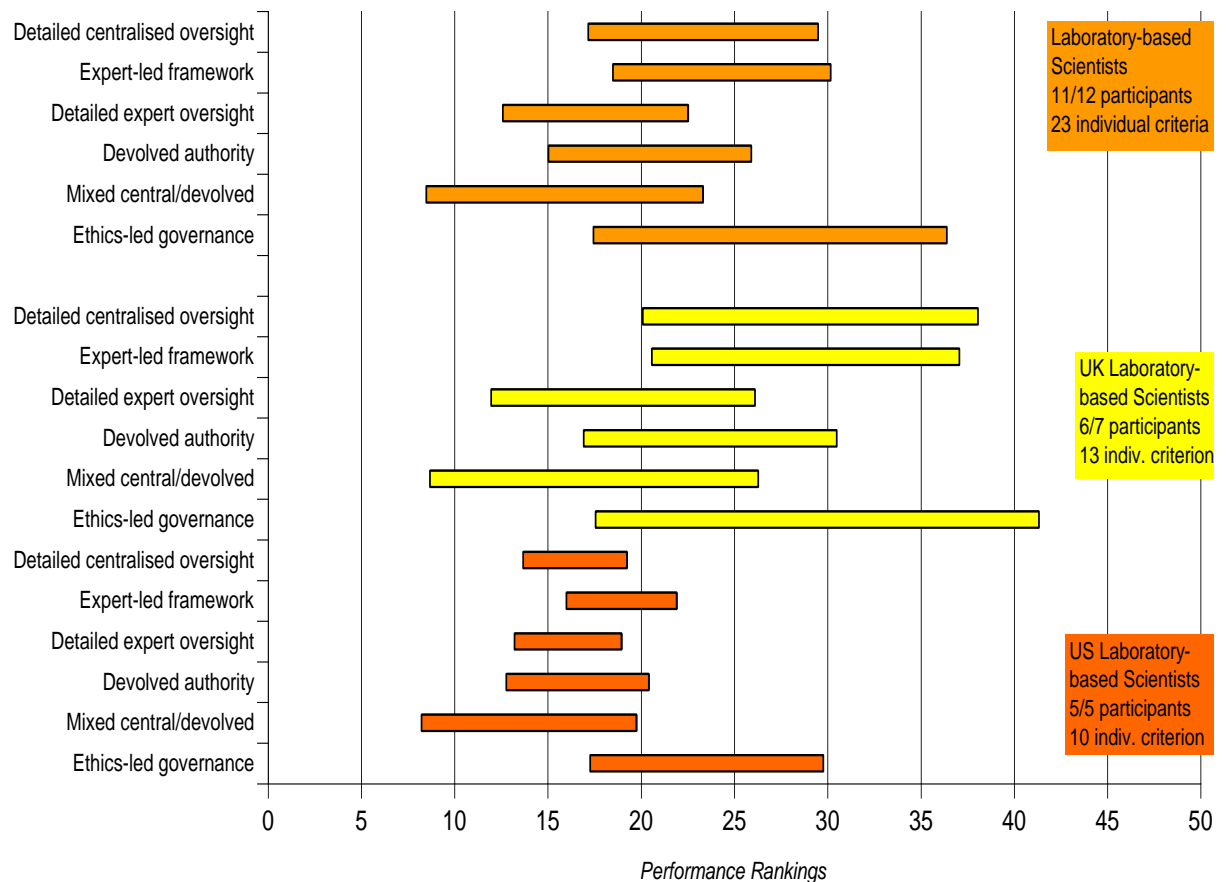
The 'go for a coffee' atmosphere is fostered, where regulation is not so oppressive that it stifles the science...[it's] about governance creating an environment that allows science to flourish and scientists not to be put off from forming collaborations or trying new things simply because of regulatory burdens (UK policy-maker 2, #C140).

The guidelines that are put forth are meant to be elastic and allow people to fit an enormous variety of situations in the framework (US policy-maker 1, #C109).

These views parallel those identified in the previous chapter where US stakeholders tended to refer to a ‘flexible and harmonised’ space for science, as opposed to the ‘protected and regulated’ space advocated for by UK stakeholders. Here, UK policy-makers and regulators also specify a protected and regulated space that should keep up with changing public attitudes. A similar link to that identified for UK perspectives in the previous chapter seems to exist between the institutional role of regulation as a means of garnering public trust and support for hESC research. This comes through very strongly at the individual stakeholder group level for UK policy-makers and regulators. We will see in the following analysis that these parallels are not always so neat, making it all the more important to note this one here. Such differences in views on how to support research reveal certain tensions in the sometimes conflicting realities of how the support processes are implemented. Good science cannot progress if it is too regulated (as indicated by a lower relative ranking of the detailed expert oversight option), but it also should not have too much flexibility (as evidenced by the lower ranking of the ethics-led governance option).

While UK and US policy-makers and regulators have been shown to have slightly diverging perspectives under this theme, this does not seem to be the case for UK and US laboratory-based scientists. As shown in Figure 7.10 below, the ordinal pattern is the same for UK and US scientists (although there are differences in uncertainty and ambiguity), however it is distinct from that of the group of policy-makers and regulators just analysed.

Figure 7.10: Rankings under UK and US laboratory scientist perspectives for ‘advancing the science’ criteria



The rankings above indicate a preference for the ethics-led option, although this is much more clearly expressed in the rankings of US than UK scientists. UK scientists, in contrast, express greater uncertainty and ambiguity and, as a result, less of a clear preference emerges among the three top performing options. Analysis of this uncertainty and ambiguity,¹¹⁸ reveals that there are differences both in expressions of uncertainty between the two groups as well as in the degrees of ambiguity. That is, UK scientists are at the same time more individually uncertain about option performance and in greater collective disagreement than are US scientists. A more detailed

¹¹⁸ See Annex J for presentation of option charts displaying this difference.

examination of the criteria comprising this issue and their use in evaluation may indicate the extent to which these differences are the result of divergent perspectives on good governance, or are attributable to some other factor.

As a group, laboratory-based scientists tend to have a ‘basic research’ framing of the scientific outcomes of hESC research; one where the outcomes are characterised primarily in terms of advances in basic biomedical science. ‘Potential’ therapeutic benefits were usually discussed as secondary considerations.

The therapeutic potential of hESCs is very far away and very hard to commercialise... [however] the benefits of understanding disease [from a basic science perspective] is huge for society (US scientist 4, #C292).

Though this concern with the importance of characterising scientific outcomes in more research-oriented ways is expressed both by UK and US scientists, there are subtle differences in the way the point is articulated. Both groups refer to the need for research support processes which provide a guiding framework for science, but UK scientists emphasise the need for long-term leadership.

It is very important to put large amounts of resources into this research as a society because the potential to move towards human therapies is so high...But it's going to be five or ten years before we get there (UK scientist 5, #C319).

Amongst US scientists, expressions about the processes which should support basic science outcomes tend to focus specifically on a desire for standardised oversight. This would provide needed stability to the field. In this, US scientists are specific about the ill-effects, both scientifically and socially, of a lack of standardisation. Governance should “*responsibly* allow scientific progress to happen” (emphasis added, US scientist 5, #C57) because “no government oversight [of this research] is a travesty...it is harmful for the research and harmful for the ethical side” (US scientist 2, #C66). The purpose, then, of a guiding framework as portrayed by US scientists seems intended to show respect for the sensitive nature of the science and to help advance the field as a whole.

Interestingly, neither UK nor US scientists address regulatory burdens when discussing good processes of research support. This is particularly interesting because most of the other stakeholder groups express concern about the impact of overly burdensome regulation on the ability of scientists to pursue their work. Scientists themselves, though, discuss only the need for policy frameworks to be ‘flexible’ or ‘responsive’. Rules are a good thing, but they have to be “responsive, so that they can change as the science changes” (UK scientist 6, #C314). However, despite not addressing such rules explicitly, they seem to implicitly in that the rankings for the more

centralised options are lower or equivalent to the more decentralised options. Thus, scientists seem most interested in freedom to pursue scientific inquiry, something held to be best found in less centralised options.

As pointed out above, with the exception of the ethics-led governance option, the rankings by bioethicists seem similar to those of the policy-makers and regulators discussed earlier. However, we do find that the framings that are revealed under this perspective vary from those of the policy-makers and regulators in important ways. Whereas policy-makers and regulators characterise hESC research outcomes in terms of the need to support ‘good’ science, bioethicists tend to characterise good outcomes in terms of the potential benefits to society. As one US academic bioethicist states, “governance must involve an innovative public policy with an optimistic view of the future of human societies that fosters more progress and innovation” (US bioethicist 4, #C277). Other bioethicists make similar points about governance leading to general societal benefit.

It [the governance framework] should start with the assumption that science can be good... to appreciate that making changes, hopefully for the better, is what makes us humans different (US bioethicist 3, #C44).

We might say, then, that in line with the disciplinary training bioethicists receive, there seems to be a framing of the scientific outcome which relies upon the medical *principle of ‘beneficence’*.¹¹⁹ Under this view, scientific outcomes must not cause net social harm, be it to public health or moral fabrics of society.

Despite these similarities in the framing of the criteria, there are differences in the way the assessments of the options were carried out. There is often a greater degree of ambiguity (meaning there is disagreement over option performance between one participant and another) amongst participants within the stakeholder group.¹²⁰ This is possibly explained by looking at the way in which ‘bioethicists’ themselves are characterised, both for this research and as observed in wider literatures. As has been pointed out earlier, the composition of national bioethics bodies often cover a wide range of individual backgrounds and disciplinary traditions extending well outside philosophical inquiry to law, theology, science, social science, medicine and more (Gottweis et al., 2009). Though all the individuals in the bioethicist perspective for the analysis here had some theoretical or practical grounding in the discipline of bioethics, a

¹¹⁹ See the definition of beneficence given in Chapter 5, p. 108, for a full discussion.

¹²⁰ See Annex J for a presentation of charts displaying this finding.

variety of primary or secondary backgrounds in different fields from philosophy to policy-making were also present.

This may help explain why two very divergent options have the highest performance rankings under this issue. The detailed centralised oversight option is a centralised, strongly regulated option whereas the ethics-led governance option has no central legislation and individual research institutions enforce their own oversight guidelines. Even though there are similar, ‘positive social’ views on hESC research as described above, we do see different framings or assumptions made in relation to its ‘implementation’ (i.e., option assessments). For example, one bioethicist working for a biotechnology industry group believes centralised systems with prescriptive regulations offer an opportunity for governments to guide the research in particular directions so that technology and innovation can benefit the public more quickly (US bioethicist 3, #A249). Another bioethicist who worked as a policy-maker for the Bush administration also believes that a centralised, regulated system could be supportive of hESC research, but for different reasons. It is his view that the detailed centralised oversight option has a high optimistic assessment under ‘advancing the science’ criteria because regulatory bodies generally get more permissive over time and are more responsive to organised scientific interests (US bioethicist 5, #A1387).

The ethics-led governance option, by contrast, has a more ‘hands-off’ and unregulated approach. In evaluating this option, one academic bioethicist makes the assumption that “if there's a positive ethical stance towards science ... there could be a lot of appropriate encouragement of science” (UK bioethicist 2, #A1063). Another comments that, under his criterion of ‘progress’, the option scores well because “experts [of any kind] are focussed on progress in the science. So an ethics-led option with high levels of expert involvement will do well here and push getting things done” (US bioethicist 4, #A1590). As both of these individuals taught ethics, the assumptions they made seem to reflect the belief that with erudite ethical input, a positive and appropriate governance environment that is mindful of societal and public views will emerge. Thus, although the criteria characterisations reveal similar framings of scientific outcomes, the option assessments reveal that the different assumptions made about option performance vary. Moreover, they vary in ways that seem dependent on the individual’s professional background. This affirms recent academic work which questions whether ‘bioethicists’

are truly objective arbiters of social and moral views (Levidow and Carr, 1997; Tallacchini, 2009), or simply introducing a new type of legitimacy ‘expertise’.¹²¹

In some ways, the perspectives of advocacy groups share certain features with those of bioethicists, which is perhaps surprising given that the two groups are often not associated. That is, advocates are often known for vociferously arguing for, often contending, policy agendas, whereas bioethicists are portrayed within official policy discourse as pragmatic deliberators about social values and cultural pluralism, arriving independently at common ground (Tallacchini, 2006). Like bioethicists, participants in the various advocacy groups tend to frame hESC research in terms of the public benefits that can be realised. However, while bioethicists stressed both medical and social good in a more substantive way focussed on consensus, advocates seem more inclined to frame public benefits in line with their individual goals. One patient advocate pointed out that there was a need for “science in the public interest...with a specific purpose...[not] just research for research’s sake” (UK patient advocate 3, #C6), while another commented that “science [itself] is driven by a societal need for medical advances” (US patient advocate 1, #C252). In both cases, ‘public’ or ‘societal’ needs are invoked, but in a way that masks the privately-held, more instrumental goals of the participants. This was also evident with those who did not support some aspect of hESC research or research governance. One policy advocate opposed to hESC research, and particularly the governance system in the UK, is concerned that commercial interests in governance are too influential. He appeals to public interests in pointing out that such commercial intervention could prevent the public from benefiting from research they are, in fact, funding (UK policy opposition 6, #C344).¹²²

This all suggests there may be a cross-cutting strategy within this group, regardless of the policy objectives being argued, of appealing to a shared sense of ‘*public good*’ in order to advance individual policy objectives. It may be for this reason that we find (as shown in the performance rankings in Annex J) a consistent pattern among all types of advocacy groups of a favourable evaluation of options with centralised oversight structures and detailed regulations. In this case, centralised regulation would ensure ‘consistency’ in the outcomes of scientific endeavours. Of

¹²¹ See the discussions in Chapter 5 (pp. 122-124) for the academic background, as well as the discussion in Chapter 8 where the empirical and theoretical strands in this regard are combined.

¹²² Only two participants opposed to hESC research and governance systems defined criteria that related to this issue. The implications of this are incorporated implicitly into the findings above and can be observed in terms of option rankings in Annex J.

course this is dependent on the governing bodies being in favour of an individual's policy objectives, and so we see optimistic and pessimistic scores reflecting either situation. An example of this is seen in the case of patient advocates, who find the 'detailed expert oversight' option to have the highest performance ranking under optimistic scores. In this option, the approval of research relies on expert-based decision-making. Many patient advocates thought experts, with a natural interest in science, could facilitate moving it forward, faster.

Among the views of industry and professional body executives within the issue of 'advancing the science', arguments for why science should be advanced seem to relate to a notion of '*scientific freedom*'. That is, there seems to be a tendency, either within the definition of the criteria or the assessments of the options under the criteria, to relate ideas about scientific freedom to the capability of firms or organisations to successfully innovate and realise commercial gains. Thus, both the quality of scientific outcomes and the process of research support are couched within a particular framing of how 'free' individuals (and their companies or professional groups) are to pursue research that is commercially or therapeutically promising.

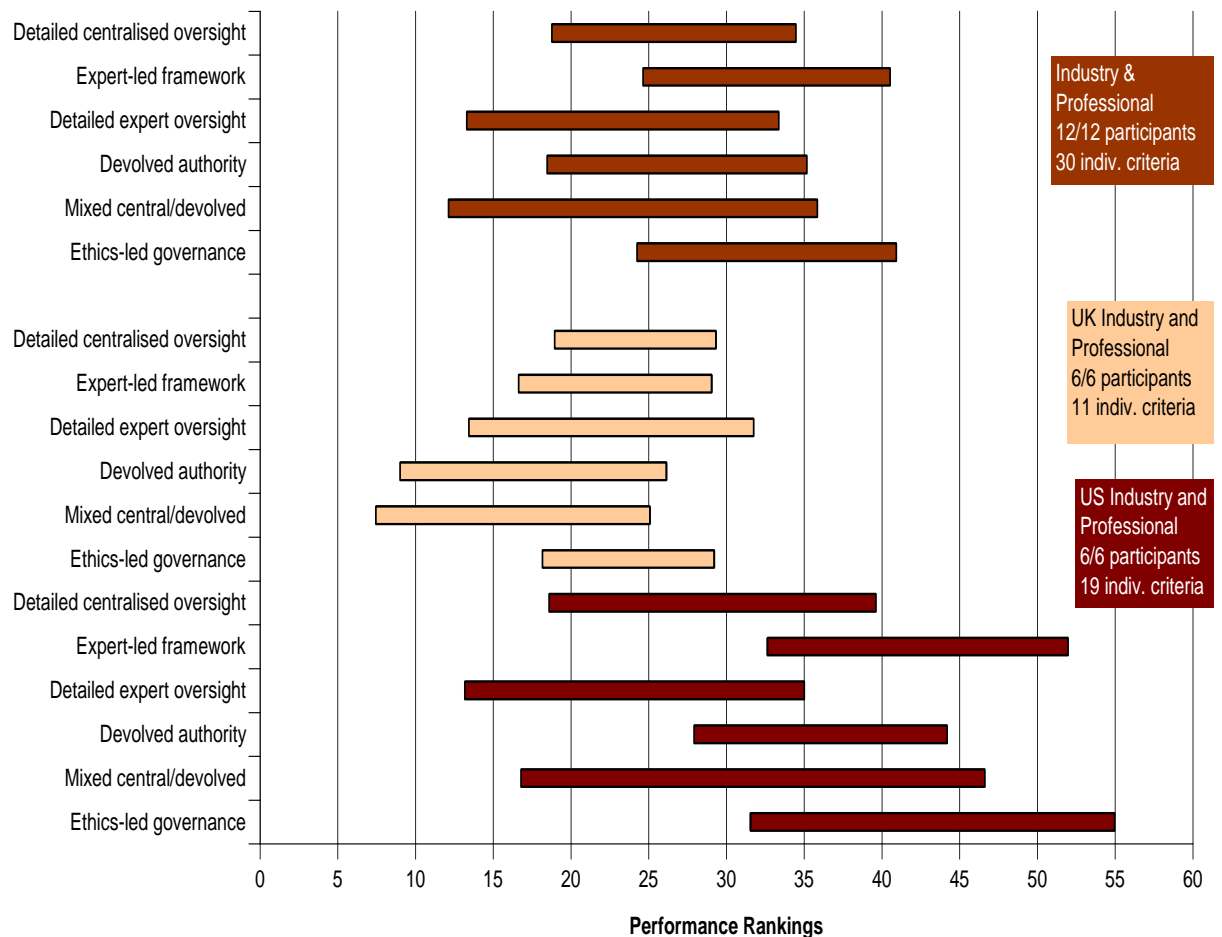
However, there is some variation in how this was expressed. The UK governance framework is permissive of hESC research, but there are many regulations that businesses must adhere to. Thus, many UK-based industry and professional stakeholders expressed concern over the "chilling effect" (UK industry executive 1, #C338) regulations can have on scientific freedom. It is not that stakeholders believe there should be no regulation, but rather it is a matter of balance. One industry executive who works in a company developing adult stem cell therapies, but looking to move into embryonic stem cell therapies, pointed out that:

The regulatory framework cannot be too rigid now, it needs to be flexible. The framework in place needs to be protective enough for safety and responsive enough to take future developments into account (UK industry executive 3, #C203).

This seems to suggest a strong relationship between concerns about good governance and the governance realities in each country. This also explains for the observed ranking differences in the two countries, shown in Figure 7.11 below. UK-based stakeholders in this group favour the detailed expert oversight option because they believed the expert-based oversight processes could give science more of a 'green light', but they do not shy away from the regulations required of this option. In contrast, US-based stakeholders clearly favour the two options where oversight of the research has little to no central

oversight and no formal regulations governing it. Moreover, US industry and professional executives express a higher average weighting for this issue of 65%, as opposed to the UK average weighting of 39%.¹²³ This shows this issue not only to be more frequently mentioned by US stakeholders, but also of greater relative importance. Again, one explanation for this could be the more restrictive climate for research in the US at the time the interviews were conducted. What is ironic, though, is that these restrictions only apply to national funding of hESC research. Privately-funded, industry-led research was not subject to the restrictions. However, the knock-on effects of such a policy climate were clearly great enough that US executives felt even more inclined to stress the importance of a facilitative governance framework for innovation.

Figure 7.11: Rankings under UK and US industry and professional body perspectives for 'advancing the science' criteria

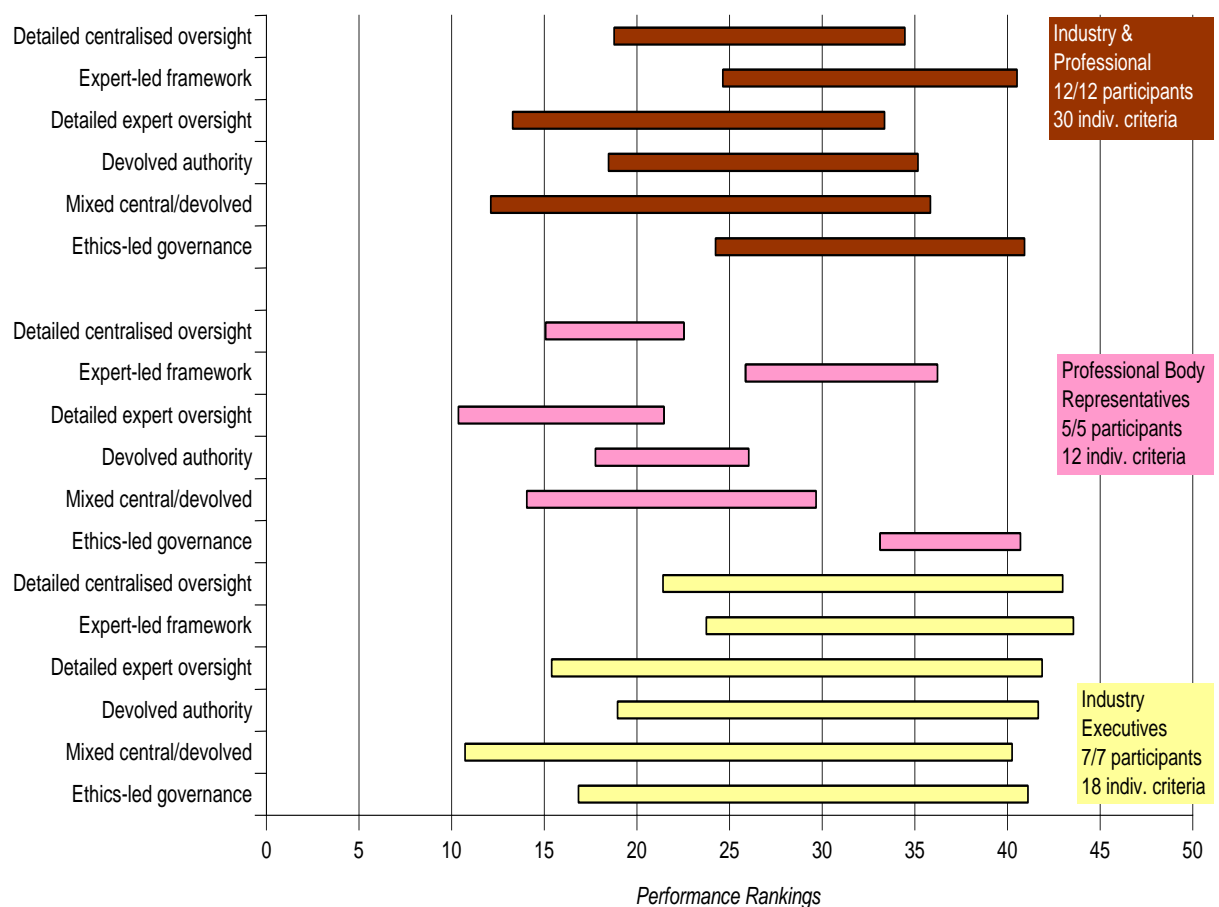


In addition to these national differences, the analysis presented earlier under all criteria suggested that the intra-perspective difference between ‘industry executives’ and ‘professional body executives’ may offer additional analytical insight into how

¹²³ A full table of weightings for all criteria discussed in this chapter can be found in Annex J.

perspectives on good governance are constructed within the ‘industry and professional’ group as a whole. As shown in Figure 7.12 below, we do see differences in the ordinal patterns of rankings between these two sub-perspectives. For the group of professional body executives, there is a clear preference for the ethics-led governance and the expert-led framework options. In contrast, the performance rankings for industry executives display a striking amount of similarity in the high end performance rankings under optimistic scores, but greater variability in the pessimistic assessments at the low end. They also seem to express much greater uncertainty and ambiguity in their assessments.¹²⁴ It is worth calling attention to the clear differences between the ranking patterns below and those of the national groupings above. These show that very different sets of assumptions can be distinguished depending on one’s affiliation with industry, professional bodies, or national contexts.

Figure 7.12: Rankings under industry and professional body perspectives for 'advancing the science' criteria



¹²⁴ As the reader will be aware by now of other features of MCM performance ranking charts which may be of interest, he will also notice the greater expressions of uncertainty and ambiguity in the performance rankings for industry executives. The charts displaying uncertainty and ambiguity are provided in Annex J and the implications have been incorporated into the analysis here.

The differences in rankings observed above are all the more interesting for the fact that, upon qualitative analysis of the criteria comprising the issue, there is little difference in the types of criteria from one group to another. Part of the explanation for the difference in performance rankings, then, seems to lie in the subtleties of participants' points of view and assumptions made about the options, both as they relate to the work of each individual. Industry executives may be more concerned about the 'bottom line', that is, whether governance will enable scientific outcomes to translate directly into commercialisation opportunities. Their option evaluations seem to illustrate the possibility that when looked at solely in terms of outcomes, multiple types of governance frameworks have almost equal potentials to enable commercial success. However, there are many pessimistic conditions under which this may not be the case.

Executives of professional bodies, on the other hand, represent a wide range of professional interests and views, which may involve diverse commercial or professional areas. Their criteria have a slightly greater emphasis on how enabling of innovation the processes of research support are, as compared with the industry focus on the outcome of innovation, itself. The subtle difference has a big impact on option assessment. For participants in professional body, the option assessments indicate a preference for governance options where there are fewer perceived roadblocks to advancing the science. These roadblocks seem to include regulation, as the two most regulated options have the lowest rankings in a 'best of the worst' and 'worst of the best' scenario. This seems to give a signal that when the emphasis is on processes that enable innovation, clear distinctions in options can be made. When the emphasis is on outcomes, there seems to be a view that, optimistically, anything could happen given the right conditions. This finding echoes one that will be discussed in Chapter 8 about the evaluation of process-based and outcome-based criteria, more generally. The next section will summarise all the findings of this section together and draw out the most important points.

7.2.3 Discussion

The discussion above has shown that for those stakeholder groups on which analysis has focused, that it is possible to discern perspectives between which there do emerge systematic patterns. These may aid analysis of how perspectives on good governance as a whole are constituted. Table 7.3 below summarises the main patterns in

perspectives on good governance under the theme ‘advancing scientific and technological trajectories of hESC research’.

Table 7.3: Summary table of patterns in perspectives under the theme ‘advancing scientific and technological outcomes of hESC research’

		Policy makers & Regulators	Scientists (Laboratory)	Bioethicists	Advocates	Industry & Professional
Advancing scientific & technological outcomes & addresses related issues in hESC research	Qualities of scientific outcomes (including therapeutic and technological development)	Emphasis on ‘good’ science	Basic science	Beneficent science	Public interest science	Innovative science
	Processes & mechanisms for research support	Establish proportionate regulation OR Ensure harmonised policies (UK/US split)	Provide leadership & guidance	Varies with participant background	Achieve outcomes through centralised processes	Ensure freedom to operate

Shading Key:

	<i>Indicates a particularly strong signal from the empirical data and emphasis is placed on these areas in the text.</i>
	<i>Indicates a clear signal from the empirical data, but findings are not always central to argument.</i>
	<i>Indicates some individual points from the analysis were of interest, but overall the findings are not central to the argument and, moreover, there was not sufficiently clear signal to merit further analysis.</i>

The distinctions and systematic patterns identified in the preceding analysis and summarised in the table above are a strong empirical finding in this area of the analysis. The perspectives that emerged under this theme clearly relate both to the *qualities* of scientific outcomes that are seen as ‘good’ and valued by different stakeholder groups, as well as the *processes and mechanisms* of research support that would facilitate the realisation of the outcomes. Not only do these perspectives emerge in a clear manner, but they differ systematically across the stakeholder groups. This is especially intriguing in the case of policy-makers and regulators and bioethicists, where the evaluations of the options share common features, but the perspectives themselves differ.

The option rankings produced by laboratory-based scientists and industry and professional body executives also shared some common features (such as the higher performance of the expert-led framework and ethics-led governance options). Both groups also spoke generally in terms of scientific freedoms or autonomy to pursue promising areas of research. However, laboratory-based scientists focussed on scientific outcomes within basic biomedical research, while industry and professional executives had an emphasis on commercial applications or therapeutic innovations. Interestingly, laboratory-based scientists did not speak very much about regulatory burdens, though this concern was expressed by members of all other stakeholder groups.

The perspectives of advocates varied the most depending on the particular socio-political view of the individual, but there were common themes invoking ideas of ‘public good’ as an important quality of scientific outcomes. Centralised processes of research support for all types of stem cell science would best enable these outcomes. This view was especially prevalent among US patient and policy advocates in favour of hESC research. One participant explained that it was like when the US waged its ‘War on Cancer’ in the 1970s (US advocate and policy-maker 8). Though the target disease was cancer, there was a positive knock-on effect for all of biomedical science.

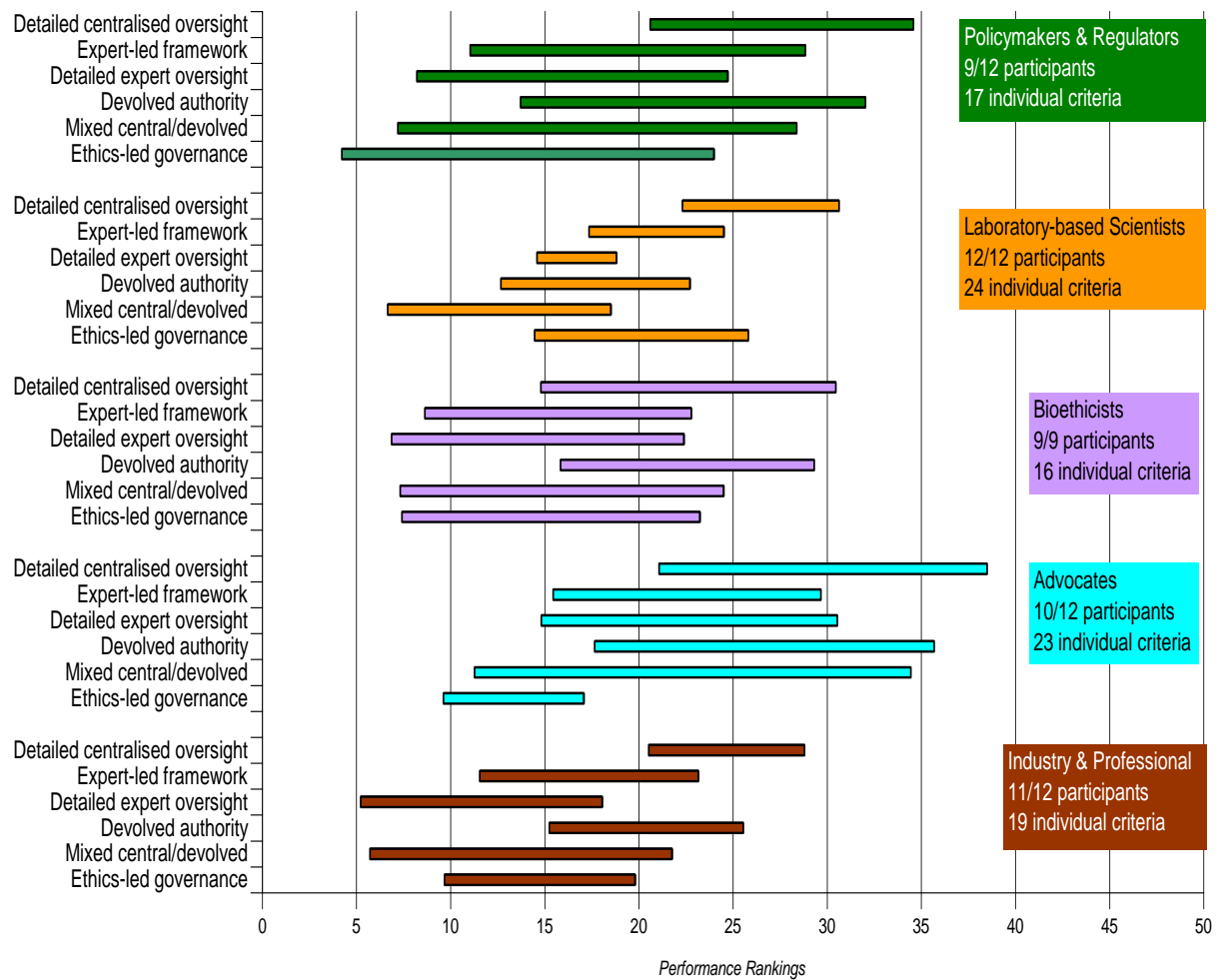
Overall, the analysis has revealed important differences in framing and related effects of socio-political points of view on option evaluations. We will now turn to the perspectives on good governance under the theme of ‘institutions and instruments of governance for hESC research’.

7.3 Institutions and instruments of governance for hESC research

7.3.1 Qualities of deliberative activities

As in the previous chapter, this section will look at the broader rankings of governance options under the issue ‘qualities of deliberative activities’, as well as two sub-issues: the ‘role of the public’ and the ‘nature of expertise’. Before discussing these, we will consider option performance under the issue ‘qualities of deliberative activities’.

Figure 7.13: Rankings under all stakeholder perspectives for ‘qualities of deliberative activities’



As we can see in Figure 7.13, some ranking patterns consistently recur. Again there is less uncertainty and ambiguity in the rankings of the laboratory-based scientists and greater uncertainty and ambiguity for the mixed central/devolved option under many of the perspectives. The detailed centralised oversight option has the highest performance for all the stakeholder groups, a feature that is particularly notable here in the perspective of industry and professional executives (as this option has not performed so well for this group under previously discussed issues). In order to best understand these patterns, we need to see how perspectives on good governance are constituted within this theme. This requires examination of option appraisals under criteria concerning different types of deliberative activities.

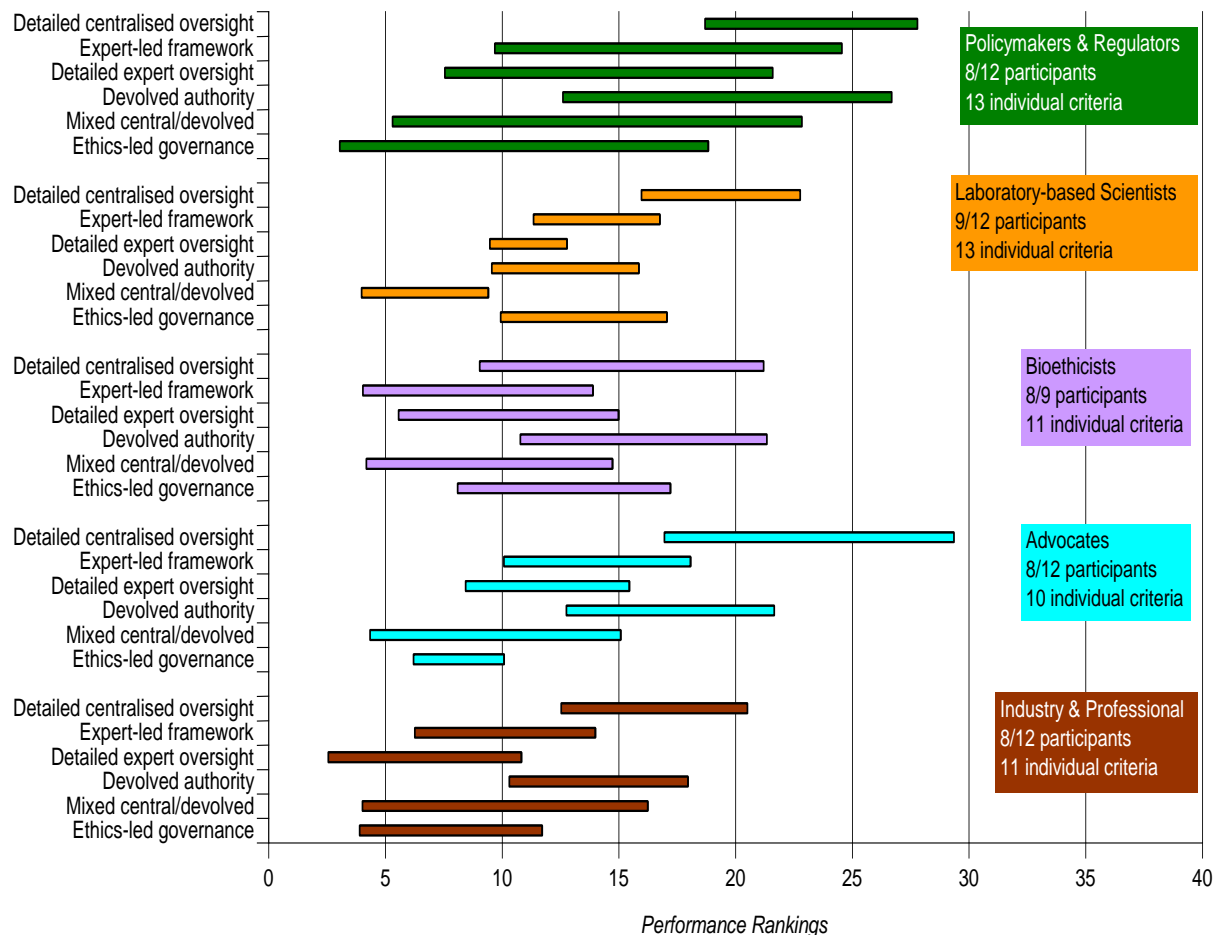
7.3.2 Deliberative activities: The role of the public

Before considering option rankings under this issue (shown in Figure 7.14), let us review the issue definition as it was used to group criteria for the analysis:

Role of the public: Criteria in this issue are concerned with how the role of the public is conceived of and defined as a part of good governance. The focus is both on how public inputs and deliberations might feed into the governance process, if at all, as well as the importance of public views on the institutions and instruments of governance itself. Thus, issues like public trust and confidence are addressed.

There are 58 criteria identified as relating to this issue and their distribution is fairly even across different stakeholder groups. Though, the individual numbers of criteria defined within each stakeholder group are relatively small, in each group over half of the participants define at least one criterion within the issue. Consequently, though we must exercise caution (as in other areas) in over-interpreting patterns arising in analysis, there do emerge some intriguing features in cross-perspective comparison.

Figure 7.14: Rankings under all stakeholder perspectives for ‘role of the public’ criteria



Perhaps the most notable feature in the figure above is the consistently high rankings of both the detailed centralised oversight and devolved authority options across all stakeholder groups (with the exception of laboratory-based scientists in relation to the devolved authority option). The fact that both of these options were consistently

evaluated so positively in relation to the other options suggests that there may be something inherent to these two frameworks that is seen to be critically important to the way in which the perspective for this issue is characterised. In addition to this feature, there is also a consistent ordinal pattern between the first three options (going down the y-axis) for all but one stakeholder group (that of bioethicists). Thus, starting with the detailed centralised oversight option and going down, the optimistic performance rankings are lower and lower.

Examination of the criteria within this issue¹²⁵ reveal differences in the way in which stakeholders characterise and conceive of the role of the public in a wider governance context. This role is either characterised in terms of the *processes* of public engagement or participation activities and the qualities which make them ‘good’, or in terms of the ‘publicly framed’ *outcomes* that institutional mechanisms should achieve. With the latter (and as in the previous chapter), the criteria emphasise features of good governance that might lead to public support, trust or confidence in hESC science and governance activities. Different emphases are placed on these two characterisations across the stakeholder groups, with corresponding implications for perspectives on good governance and option evaluations.

Policy-makers and regulators predominately characterise the issue in terms of *outcomes* that are in turn framed in relation to the public trust and confidence that different institutional mechanisms of governance should achieve. Whether discussing the importance of ‘transparency’ (various participants, #C264, #C119, #C171, #C300, #C270) or the need to ensure ‘accountability’ and ‘objectivity’ in decision-making processes (UK regulator 4, #C120, UK policy-maker 3, #C174), most of the policy-makers and regulators interviewed justify their criteria in the context of public trust and legitimacy. As one US policy-maker comments, ‘good’ governance needs to

win and maintain popular support as legitimate, safe and appropriate... Popular legitimacy [is defined] as the public accepts this is a legitimate way to govern it research] (US regulator 4, #C67).

Another US, state-based policy-maker defines two separate, but inter-related criteria about public trust. In this way she emphasises the importance of “engendering” public trust both through the governance processes put in place, such as “appropriate representation and consideration of different viewpoints” (US policy-maker 8, #C234), as well as through the implementation of policies that protect the public from risk. The

¹²⁵ The reader is again reminded, as with all qualitative material presented in these chapters, that a full list of criteria is provided in Annex H.

linking of the two is important and emphasises the outcome focus. “Even if you have a process in place that fosters public trust, it means nothing if the follow-through is not there” (US policy-maker 8, #C235).

It is not only the consistently expressed convictions favouring outcomes of public trust which characterise this perspective, but also the instrumental way in which this is pursued. That is, in seeking public trust as a specific outcome of a governance option, policy-makers and regulators reveal an instrumental¹²⁶ imperative in their appraisal of governance activities. The perspective of policy-makers and regulators is not the only place where this is found.

Laboratory-based scientists discuss features of public engagement with a clear outcome focus and instrumental motivation. However, the outcomes are framed in relation to public confidence in the science, not in governance itself. Thus, many criteria seem to reflect a view that if engagement is designed so as to make the public feel they have a stake in governance decisions, then public trust in both the governance framework, and the conduct of the science, will follow. It is important, then, that there is not only ‘support from stakeholders’ (UK scientist 3, #C194) in the governance structures, but also that “society should have some say in setting the guiding principles” for these structures (US scientist 4, #C287).

Within this issue, then, laboratory-based scientists are concerned with how processes can be designed so as to achieve particular outcomes. With this come clear ideas about which governance frameworks best achieve this. In fact, the clear distinctions in ranking patterns are quite remarkable and suggest a convergence in views amongst the individual participants.¹²⁷ Detailed centralised oversight, with clear rules, and a mix of democratically informed expert bodies was the preferred option. Options that did not include democratic participation principles or had unclear national rules were negatively evaluated. An interesting exception to this is the ranking of the ‘ethics-led governance’ option. Although, there is no national oversight, this option is attributed high performance under optimistic scores. A possible explanation for this anomaly lies in some participants’ interpretation of the working of ethics bodies. There was a shared view that ethics bodies, by their very remit and nature, reflect on public views. It is

¹²⁶ See the discussion in Chapter 8 for a full description of the implications of such instrumental imperatives. The concept is based on the body of literature introduced in Chapter 3 on p. 52-53.

¹²⁷ Though all the criteria defined by this group express ideas about the role of the public in similar ways, it should be noted that the majority of the criteria are defined by UK-based laboratory scientists. The implications of this for the analysis presented here are not great.

therefore seen to follow automatically that any governance based on their guidance would be publicly accepted. As was pointed out in earlier discussion,¹²⁸ this suggests that the claims of ethics bodies are uncritically adopted by some stakeholder groups and perhaps contributes to their perceived legitimacy as a new type of expertise.

Another stakeholder group that characterises the issue in terms of outcomes consists of the industry and professional body executives. Though it is difficult to determine any specific patterns in the ways this issue is framed, there is some general concern with losing public trust. Thus, some wanted to ensure that public engagement happened in some way in order to “avoid mistrust” (UK professional executive 4, #C331), or to achieve “trust and support” in the processes of governance already in place (UK industry executive 4, #C297). Given the similarities between the ranking patterns for this stakeholder group and that of the policy-makers and regulators, it is tempting to conclude that their respective perspectives on the role of the public are similarly constituted (that governance should foster public trust, confidence or acceptance). While this may be the case, the signal is not sufficiently clear to warrant much further discussion.

The final group that shares an outcome-focused perspective concerning the role of the public are patient advocates and advocates of permissive hESC research policies. Like scientists, participants in this group seem at first to be discussing process-based issues about more openness in public engagement, but this is done with the intention of ensuring specific outcomes are achieved from them. In the case of patient advocates, these outcomes are usually public support for hESC science. There seems an implicit expectation that openness in public engagement will lead to greater public support for advances in hESC research.

This is evidence for a more general instrumental tendency to frame notions of good governance in terms of more specifically desired policy objectives. For example, within the criterion ‘meeting society’s needs and interests’, one participant stressed that there should be “room for society to move or drive the research based on their needs, [and] by needs of society I mean the needs for medical advancements (US patient advocate 1, #C251). Another patient advocate claimed that public trust and engagement went hand-in-hand. Trust was needed to push the science forward, but engagement was necessary to establish public trust in the first place (UK patient advocate 3, #C1). In

¹²⁸ See the discussion in Chapter 6, p. 154.

both cases, the underlying goal is advancing the science, but the framing is in terms of allowing ‘room’ for society to be engaged on the issues.

While the previously discussed stakeholder groups emphasise outcomes over process, the perspective of bioethicists is characterised more by process-based concerns, often irrespective of the outcomes that might be achieved. This reveals a more normative imperative.¹²⁹ With varying emphases on ensuring, for example, that ‘real public discourse’ is integrated into the governance model (US bioethicist 3, #C39) or that the “values of the community are expressed” (US bioethicist 2, #C165), criteria within this issue all aim (implicitly or explicitly) to ensure there is broad representation of social and cultural views.

However, this desire for pluralism is tempered for some by a note of pragmatism. That is, some bioethicists acknowledged the ‘trade-off’ that needs to occur in order to move forward with the policymaking process:

It’s about pragmatically striking the right balance between facilitating the research whilst maintaining public support for it (UK bioethicist 4, #C128).

[It’s about] cultural relativism and pluralism. How you deal with contexts and cultures, but recognise that there is a limit to this? Governance should allow for this trade-off to occur... (US bioethicist 2, #C165).

This tension between pragmatism and pluralism is perhaps more apparent in the option assessments. There is a more positive assessment of options displaying clear mechanisms for public engagement, as well as some element of centralisation and regulatory oversight. These latter features help ensure a clear path along which policy decisions can eventually be made. Thus, perhaps more explicitly so than other perspectives, it seems bioethicists are grappling with the desire to see inclusion of a wide range of public views, but not in such a way that paralyses the policy process.

Finally, policy advocates opposed to hESC research are the only group which tends to focus primarily on the importance of openness as a good quality with few caveats attached to it. There is a greater tendency to express more ‘normatively’ derived criteria, addressing: *i*) a “democratic principle of control” where “as much public debate as possible” informs the discussions (UK policy opposition 6, # C340); *ii*) a broad “framing” that “ensures no views are excluded at the start of the discussion” (UK policy opposition 1, #C132); and *iii*) the need for “reflective expertise” (US policy opposition 2, #C220) that assumes a balance between democratic voting and expert input.

¹²⁹ Again, this concept is grounded in the literature presented in Chapter 3 and discussed more fully in relation to the empirical findings in Chapter 8.

We have seen how patterns in perspectives can be discerned by looking at the relative focus on processes or outcomes of public engagement and the role of the public in governance.¹³⁰ We will now consider stakeholder views on the nature of expertise before drawing together the analysis under this theme of good governance.

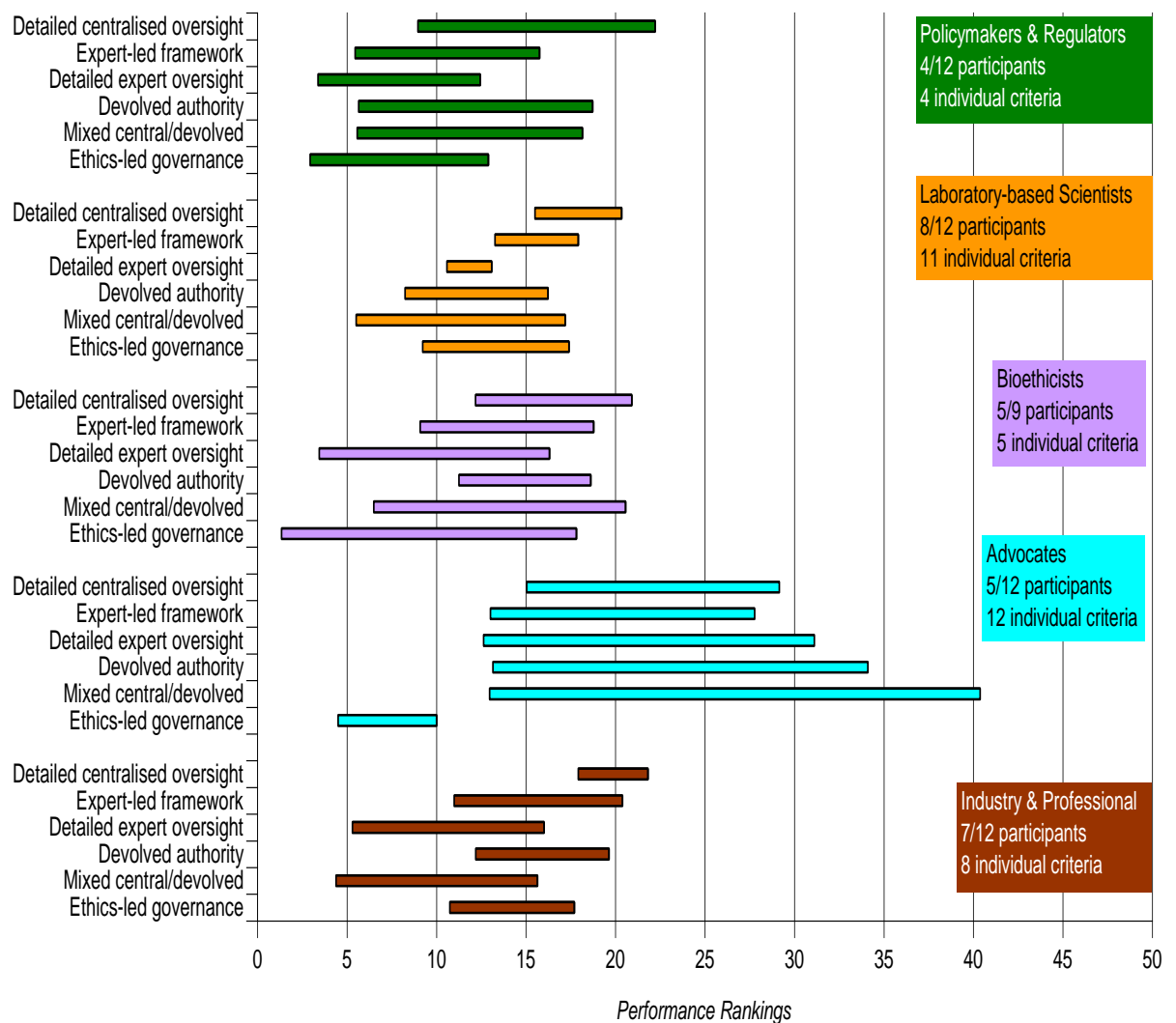
7.3.3 Deliberative activities: The nature of expertise

As introduced previously, the issue ‘nature of expertise’ is used to group criteria if they fall within the scope of the following definition:

***Nature of expertise:** Criteria relating to this issue are concerned with the features and characteristics of expertise within the governance framework. They focus on issues like the composition of expert bodies, the quality of advice that is provided, the types of deliberations that occur, and the qualities of the processes of input themselves as they reflect on the wider role of expertise in a context of good governance.*

Figure 7.15 below shows the rankings under this issue for the five stakeholder groups.

¹³⁰ Although they were not discussed here, the perspectives of industry and professional executives within this issue are included in the summary table and the discussion at the end of this section. However, the findings were not deemed to be sufficiently robust or clear to include in the analysis presented above.

Figure 7.15: Rankings under multiple perspectives for ‘nature of expertise’ criteria

A notable feature of the performance rankings above is the relative number of individual criteria defined by each perspective and corresponding mean weightings in comparison with the previous issue, ‘the role of the public’. Table 7.4 below shows the mean weightings across the issues within this theme in direct comparison. Laboratory-based scientists, industry and professional executives and advocates define similar numbers of criteria for each issue and assign relatively equivalent importance to each. However, both ‘bioethicists’ and ‘policy-makers and regulators’ define less than half the criteria for the former than the latter and assign relatively less importance to these criteria. This finding in and of itself is intriguing. This need not imply that these groups marginalise considerations of expertise, but rather that they may frame good governance more in terms of the impact and perceptions of the public than on the basis and nature of expert advice. Further comments on the implications of other weightings will be made in the discussion below.

Table 7.4: Criteria and mean weightings for ‘role of the public’ and ‘nature of expertise’

Criteria Type	Advocates	Bioethicists	Industry & Professional	Policy-makers & Regulators	Scientists (Labs)
Role of the public	8/12 participants 10 criteria; Mean weighting 20%	8/9 participants 11 criteria; Mean weighting 20%	8/12 participants 11 criteria; Mean weighting 14%	8/12 participants 13 criteria; Mean weighting 20%	9/12 participants 13 criteria; Mean weighting 18%
Nature of expertise	5/12 participants 12 criteria; Mean weighting 18%	5 participants 5 criteria; Mean weighting 12%	7/12 participants 8 criteria; Mean weighting 15%	4/12 participants 4 criteria; Mean weighting 7%	8/12 participants 11 criteria; Mean weighting 17%
Qualities of deliberative activities	10/12 participants 23 criteria; Mean weighting 40%	9 participants 16 criteria; Mean weighting 32%	11/12 participants 19 criteria; Mean weighting 29%	9/12 participants 17 criteria; Mean weighting 27%	12/12 participants 24 criteria; Mean weighting 34%

There are three different ways that participants characterised the ‘nature’ of expertise in criteria under this issue. First, expertise is discussed in terms of what qualifies someone as an ‘expert’ or what the *composition* of expert decision-making bodies should be. Second, expertise is characterised in terms of the *processes* of expert deliberations in the way they consider evidence and make decisions or provide inputs to policy-makers. Finally, the nature of expertise is discussed in terms of the *outcomes* of expert deliberations. In this, the focus is not necessarily on specific recommendations, but on the content of the evidence, advice or decisions made.

Advocates display the greatest divergence in ordinal patterns of rankings under this issue, compared with the ‘role of the public’. However, though 12 criteria are defined under ‘nature of expertise’, this is only by five individuals – mostly UK policy advocates favouring more restrictive governance of hESC research. Their criteria reflect this critical position, pointing out the importance of balanced, representative expertise that includes the views of all publics, not just those who support hESC research.¹³¹

Discussing criteria in this group, participants are comprehensive – covering in each case all three aspects of expertise discussed above. The distinguishing feature of many of the criteria and their use in the assessments is an emphasis on the ‘openness’ of the process to multiple points of view. In this, it is seen as important that experts are not “captured” by special interests, powerful actors or particular “world views” (UK policy opposition 6). While some policy advocates were more direct in their criticism of

¹³¹ This point is particularly relevant in the case of the HFEA where, as was noted in the discussion of the policy literature in Chapter 5, the only experts allowed to sit on the regulatory body are those who are supportive of hESC and other types of embryo research.

particular expert inputs,¹³² most express a desire for expertise to be broad, diverse and inclusive of lay members (various participants, #C116, #C180, #C130, #C343); provide high quality advice based in both science and ethics (various participants, #C197, #C198, #C345); and be open to alternative points of view (various participants, #C342, #C134, #C135, #C198).

While advocates' criteria cover all three aspects of expertise, laboratory-based scientists' criteria focus on the *composition* of expert bodies, specifying they should be broad, multi-disciplinary and representative of public views through the presence of lay members. Scientists also focus on the *processes* of expert inputs in a wider governance context. Thus, criteria which alternately discuss the "balance" expert advice needs to help achieve in society (UK scientist 3, #C193; US scientist 4, #C288), the "responsibility" experts have to engage with society about what kinds of science are appropriate (UK scientist 5, #C320), the principles of "accountability" experts should operate under (US scientist 5, #C61) and the "freedom" from political influence they should enjoy (US scientist 1, #C209) all contribute to the notion that expertise plays an important, cross-cutting role in good governance.

Finally, industry and professional body executives defining criteria within this issue all focus in some way on the appropriate composition of expert bodies. This emphasis is captured particularly well by one participant in her evaluation of the detailed expert oversight option when she asks "the [real] question is *who* is an expert?" (emphasis added, UK professional executive 5, #A874). In considering this, UK participants in this group particularly stress the importance of including a commercial view on expert bodies. One UK industry executive comments that membership selection for regulatory bodies "doesn't necessarily reflect the needs from a business perspective" (UK industry executive 3, #C204). The three US-based industry and professional executives who define a criterion under this issue do not stress the commercial side of expertise explicitly, but rather focus on the importance of 'consistency' in composition and interpretation (US industry executive 1, #C348), the 'scientific integrity' of the experts (US industry executive 4, #C296), and the importance of having "highly trained, currently practicing scientific experts in the room at all times" (US professional

¹³² For example, one UK policy advocate in describing his criterion about 'democratic ethics' expressed his concern that 'real public ethics' weren't being taken into account within expert advisory processes: "*What we currently have is an academic, philosophical kind of bioethics, which is inadequate for dealing with the issues that these technologies raise... This type of ethics has evolved to be acceptable to governments and scientists and experts who sit on policymaking bodies...*" (UK policy opposition 6, #C342).

executive 5, #C229). This focus on appropriate expert accreditation is also evident in option evaluations, with options that specify a ‘balance’ in experts on decision-making bodies attributed higher performance.

In summary, although the findings relating to this issue are more tentative for some perspectives due to the relatively lower number of criteria and associated weightings, there do seem to be clear contrasts in characterisations of the ‘nature of expertise’ across different stakeholder groups. These are most clearly seen within the advocates perspective, where the ranking patterns are most divergent. We turn now to a general discussion of the theme as a whole before summarising and concluding the chapter.

7.3.4 Discussion

Table 7.5 below summarises the main patterns in perspectives on good governance under the theme ‘establishes appropriate institutions and instruments for hESC research’. Where the perspective is indicated in italics, conclusions are offered tentatively due to the relatively small number of interviews or lack of clear signal as to the characterising of the perspective in question.

Table 7.5: Summary of patterns in perspectives on the theme ‘establishes appropriate institutions and instruments for hESC research’

		Policy-makers & Regulators	Scientists (Laboratory)	Bioethicists	Advocates	Industry & Professional
Establishes appropriate institutions & instruments for hESC research	Qualities of deliberative activities: publics	Outcomes: Ensure public trust through governance institutions	Outcomes: Gain public support through public engagement / education	Outcomes and processes: Pragmatic pluralism	Processes (some outcomes): Promote openness in engagement activities	<i>Gain public support</i>
	Qualities of deliberative activities: expertise	<i>Process- based: Balanced views</i>	Composition and Process- based	<i>Purpose- based: Informed decisions</i>	Composition, processes and outcomes: representative and transparent	Composition- based: ‘Who’ is the expert?

Shading Key:

	Indicates a particularly strong signal from the empirical data and emphasis is placed on these areas in the text.
	Indicates a clear signal from the empirical data, but findings are not always central to argument.
	Indicates some individual points from the analysis were of interest, but overall the findings are not central to the argument and, moreover, there was not sufficiently clear signal to merit further analysis.

There are a number of clear patterns and points of divergence and convergence amongst the perspectives. Criteria about the role of the public divided neatly between a process or outcome focus, with outcomes around public trust or support for hESC research being emphasised most strongly. However, the articulations of this outcome

focus varied. Despite nuances in the perspectives, performance evaluations of the governance options under this issue exhibit very similar patterns. This suggests that features of the detailed centralised oversight and devolved authority options best fulfil this type of good governance criteria, albeit in different ways and with varied emphases according to individual perspectives.

Criteria concerning the ‘nature of expertise’ fell into three types: composition-based, process-based, or outcome-based. While some stakeholder groups did not comment extensively on this issue, those that did revealed a basis for distinguishing perspectives in ways that resonate with those evident under the issue ‘role of the public’. The final discussion will summarise the main patterns in perspectives on good governance that have been identified throughout this chapter.

7.4 *Final discussion*

This chapter has analysed the constituting of stakeholder perspectives on good governance of hESC research. In relation to the hypotheses set out at the beginning of this chapter, we can now tentatively conclude that: 1) it is possible to discern discrete perspectives on good governance across the different types of stakeholder groups; 2) criteria definitions and option assessments allow identification of more specific patterns within these perspectives; 3) the distinguishing features of these stakeholder perspectives contrast with those of either of the overarching national perspectives identified in the previous chapter; and 4) these conclusions have implications for wider theory-making. Table 7.6 provides a summary of the main patterns in perspectives according to the themes of good governance.

Table 7.6: Contrasting perspectives on themes of good governance

		Policy-makers & Regulators	Scientists (Laboratory)	Bioethicists	Advocates	Industry & Professional
Advances scientific & technological outcomes & related issues in hESC research	Qualities of scientific outcomes (incl. technological & therapeutic development)	'Good' science	Basic science	Beneficent science	Public interest science	Innovative science
	Research support	Proportionate regulation & Harmonisation (UK/US split)	Leadership & Guidance	Dependent on background	Centralisation (to achieve specific outcomes)	Freedom to operate
Establishes appropriate institutions and instruments for hESC research	Qualities of deliberative activities: publics	Outcomes: Ensure public trust through governance institutions	Outcomes: Gain public support through public engagement / education	Outcomes and processes: Pragmatic pluralism	Processes (some outcomes): Promote openness in engagement activities	<i>Gain public support</i>
	Qualities of deliberative activities: expertise	<i>Process- based: Balanced views</i>	Composition and Process- based	<i>Purpose- based: Informed decisions</i>	Composition, processes and outcomes: representative and transparent	Composition- based: 'Who' is the expert?
Identifiable social & cultural bases of good governance	Bases of trust and legitimacy	Institutional	Evidence-based	Pluralism	Public good in the eye of the beholder	Professional representation

Shading Key:

	Indicates a particularly strong signal from the empirical data and emphasis is placed on these areas in the text.
	Indicates a clear signal from the empirical data, but findings are not always central to argument.
	Indicates some individual points from the analysis were of interest, but overall the findings are not central to the argument and, moreover, there was not sufficiently clear signal to merit further analysis.

This table summarises the distinguishing, key characteristics of divergent stakeholder perspectives on good governance. However, to avoid over-interpreting the nuances, complexities and contingencies, this summary focuses only on the principal features that have emerged from the discussion. Distinctions between perspectives under the first theme ('advancing scientific and technological outcomes') are the strongest and most notably divergent amongst the stakeholder groups. Perspectives varied in the *qualities* of scientific outcomes described as desirable, the *processes* of research support required to achieve the outcomes and in the ways each were ultimately evaluated in the context of the options. In other words, both the quantitative ranking

patterns and qualitative distinctions between perspectives indicate significant contrasts in the socio-political framings of this theme employed by different stakeholder groups.

Perspectives on the theme around ‘establishing appropriate institutions and instruments for hESC research’ also vary, but in less markedly divergent ways from the scientific theme. Here, some notable similarities emerge around otherwise contrasting perspectives, concerning both ranking patterns and qualitative features of the underlying framings. However, distinctions concerning tendencies to adopt an outcome or process focus on the role of the public or the nature of expertise are found. In some cases, the focus differed between the two types of criteria within a single stakeholder group (as the case for laboratory-based scientists), but for others the relative focus was consistent (as is the case of advocacy groups).

Considering all perspectives together, it is possible to make some broader observations concerning social and cultural aspects of trust as these relate to general notions of good governance in this area. Among policy-makers and regulators, there is a consistent tendency to highlight institutionally-based characterisations of good governance, involving ‘proportionate regulation’ or ‘harmonised oversight’. This is associated with a tendency to *invoke trust* in framing good governance, seemingly in order to win support for policy actions. Thus, while criteria about trust were often instrumentally motivated in this way, criteria about legitimacy tended to be framed more normatively. Concerns such as the representativeness of the process, the fulfilment of democratic norms and the objectivity with which policy-makers acted, all were expressed without reference to privately desired ends.¹³³

Laboratory-based scientists tend unsurprisingly to be in favour of hESC research and frame scientific outcomes correspondingly. Yet they still express an acute concern with the public’s perception of the research they conduct. This exposes a tension between engaging the public because it is the ‘right’ thing to do and engaging so that the public can be better educated and more trusting of the work of scientists. Similarly, engagement of expertise in regulation was seen as needing to be broad and diverse – both as normatively good qualities in their own right, but also because these might lead to more ‘informed’, ‘realistic’ and generally ‘better’ regulations for hESC science. Thus, for this stakeholder group, it seems that framings of ‘trust’ and ‘legitimacy’ reflect a faith that *independent, evidence-based* and *informed* governance will result in the ‘right’ attitudes and decisions for science.

¹³³ See the discussion in Chapter 8 for the analysis of these term and their significance for the thesis.

Bioethicists invoke ideas about cultural pluralism, whether discussing how best to advance the science in accordance with principles of beneficence or in engaging with the public. Trust and legitimacy, then, seem to have a basis in the extent to which *cultural pluralism* were seen to be reflected in governance. However, this was juxtaposed with a need for pragmatic policy-making. This inter-linkage between pluralism and the realities of the policy process has implications which are discussed more fully in the next chapter.

Like bioethicists, the perspectives of various advocates seem to share a similar tendency to invoke ‘societal’ and ‘public’ interest, but in ways that depend on the theme of good governance in question. In some cases, invoking the ‘public interest’ seems to reflect a rhetorical strategy aimed at advancing rather different policy agendas. For others, trust and legitimacy are based more on how *public good* is revealed through the ‘*eye of the beholder*’. The finding that the heterogeneous nature of this grouping of stakeholders yields the most divergent performance rankings of any perspective, helps to confirm the consistency of the other perspectives (relative though this may be).

Finally, it emerges across all issues that the rankings under industry and professional body perspectives tend to diverge the most from those of the other stakeholder groups. Industry and professional executives tended to adopt an innovation focus, with options favoured by this group being those involving greater decentralisation and those which might best afford a ‘license to operate’. Under this view, trust and legitimacy, are based on the extent to which *professional and commercial needs* are accounted for in the governance framework.

The final discussion chapter, Chapter 8, builds on – and draws together – the findings and analytical interpretations introduced in this chapter and the two previous ones, as well as introducing some new ones. The main aim is to explore links with existing academic literature reviewed earlier and specify the exact theoretical and practical contributions of this research.

8. Discussion: bridging the empirical and theoretical

8.1 Introduction

The previous three chapters have explored a variety of empirical grounds for discerning contrasting perspectives on good governance within: *i)* formal US and UK policy documents; *ii)* findings from 57 MCM interviews comparing between US and UK perspectives; and *iii)* findings from 57 MCM interviews comparing between different stakeholder perspectives within and across the two national settings. The remaining task is to integrate these empirical strands with each other and with theoretical issues concerning ‘good’ governance provided in earlier chapters. This chapter will therefore address four main areas which cut across and interlink the empirical findings and theoretical literatures.

In Section 8.2, we consider a recurring theme in the previous three chapters concerning distinctions between *process-* and *outcome-based* characterisations of good governance. We will examine implications of particular rationales and motivations behind such characterisations (based on theoretical distinctions discussed earlier between normative, instrumental and substantive imperatives in policy appraisal). Therefore, we will address a recent and developing body of theory in technology appraisal and democratic deliberation.

In Section 8.3, we will focus in greater detail than hitherto on themes of ethical and moral awareness in good governance – and the ways in which these issues were more pronounced in findings from the MCM interviews than the policy documentation. The normative implications of these findings for policy-making will also be discussed. Related to this, Section 8.4 will consider the implications of the patterns and relationships observed here between the perspectives on good governance of bioethicists (on the one hand) and policy-makers and regulators (on the other). This will offer a new empirical basis for returning to theoretical and critical literatures on this issue introduced earlier in this thesis.

Section 8.5 will consider a comparative STS perspective – specifically Jasanoff’s concept of ‘civic epistemologies’ – concerning the distinct ways knowledge is produced in different national contexts. Points of similarity and divergence will be explored between these ideas and the empirical findings obtained here. The discussion

chapter will end there, but will lead directly into the concluding section of this thesis, Chapter 9. Here, a final summary for the thesis is presented, with the main contributions of the thesis reviewed, tentative recommendations offered for policy making in the area of hESC research and suggestions for further research made.

8.2 Exploring normative, instrumental and substantive motivations in appraisal

8.2.1 Introduction

Stirling (2008) argues that apparently stark dichotomies between expert analysis and participatory deliberation tend to mask a series of more nuanced cross-cutting contrasts between different imperatives, intentions or motivations for ‘public engagement’ in social appraisal of alternative technology strategies. As was discussed in earlier chapters, rather than focussing on these dichotomies (and the implications for decision making that might result), he suggests that attention might more fruitfully be devoted to improving understanding of the rationales and motivations that lie behind the design of different types of appraisal (both expert and participatory). To this end, Stirling builds on prior work by Fiorino (1989) and Fineberg *et al* (1996) to distinguish three basic imperatives, or motivations, that may lie behind the design or appreciation of social appraisal in technology governance: normative, instrumental and substantive. As expressed in the literature, these observations are based on interpretive analysis, rather than systematic empirical examinations. Therefore, the characterisations of good governance across contrasting stakeholder perspectives in ‘real world’ settings as provided by this thesis may offer valuable insights. The task here, then, is to conduct this empirical examination.

As argued and demonstrated in the preceding discussions, MCM is a method for eliciting nuances of framing in the social appraisal of alternative science and technology policies (in this case, options for governance of hESC technologies). MCM is therefore a suitable tool with which to conduct an original empirical test of the theoretical case made by Fiorino, Fineberg *et al.* and Stirling for the three distinct motivations underlying social appraisal, itself. If the distinctions are confirmed as salient across contrasting cases and divergent perspectives, then this thesis will have directly addressed a significant strand of thinking in recent theoretical literature on technology governance.

The first of these underlying drivers in social appraisal (to briefly review the argument outlined in earlier chapters¹³⁴) are **‘normative’** issues. These focus on variously-conceived qualities in the *processes* of appraisal (Pellizzoni, 2003; also as interpreted by Stirling, 2008). They relate in diverse ways to the distinguishing of a particular governance framework as ‘good’ simply on the grounds that certain practices or processes involved are judged in and of themselves, *in principle*, to be inherently ‘*the right thing to do*’ (for instance, involving democratic inclusion as a self-evidently ‘good’ feature of process, irrespective of the outcomes). Accordingly, it was possible to identify a subset of participants’ process criteria as being framed so as to reflect their ‘normatively’ good nature, in and of themselves, without regard to the consequences. Examples of such normatively-motivated criteria for good governance include features like ‘public reason’, ‘openness’, ‘legitimacy’, ‘representativeness’ and ‘transparency’.

The next two types of imperatives are ostensibly concerned with *outcomes* of appraisal (Pellizzoni, 2001; also as interpreted by Stirling, 2008), but they vary in important ways. **‘Instrumental’** imperatives are concerned with the realisation of particular ends. Here, ‘good governance’ is judged primarily not by reference to process, but in terms of outcomes in the form of prior, *privately-defined* policy goals. Thus, in the context of the present analysis, instrumental framings of good governance are (usually implicitly) primarily concerned with achievement of specific organisational, policy or scientific ends, and focus not on evaluating the ends themselves, but the means by which they may best occur.

The other outcome-based imperative (the third and final imperative overall) is **‘substantive’**. By contrast with the privately-held objectives driving instrumental motivations, substantive imperatives centre on *publicly-deliberated* and *consensual* societal values such as public health or equity. Thus, though the focus of substantive criteria of good governance is also on a set of desired ends, these ends are defined (usually more explicitly) in broad societal terms. Though substantive ends may be conceived in different ways, they are not usually controversial in broad terms as objectives (for example ‘health protection’ is generally an acceptable aim), in the way that instrumental ends often are.

Against this background, we can pose three broad-based questions which reflect the hypotheses of this thesis. First, does the threefold distinction between normative, instrumental and substantive imperatives in good governance comprehensively

¹³⁴ See the discussion in Chapter 3, p. 52-53.

characterise and adequately partition the empirically-elicited criteria? In other words, how well does the articulation of criteria by interviewees resonate with the three theoretical dimensions? For example, are there significant numbers of ambiguous or hybrid criteria, is one category barely represented, or does a fourth category emerge? Second, are there differences apparent in performance patterns depending on whether governance frameworks are appraised under normative, instrumental or substantive criteria? Third, does this conceptual scheme offer a basis for explanatory discussion of the drivers of contrasting framings adopted under different perspectives (as explored in this thesis)? Depending on the answers to these questions, we may also be able to ask whether particular types of perspectives tend to favour normative, instrumental or substantive issues and how.

Some of these questions, particularly the first two, have been previewed in earlier chapters when relevant to discussing the perspectives within the themes of good governance. However, the issues have not been considered ‘holistically’ and there has not been a critical examination of theory in light of the empirical findings. It is this latter point on which the discussion in Sections 8.2.3 and 8.2.4 will most heavily focus. The presentation of empirical findings, themselves, will first be done in Section 8.2.2.

8.2.2 Exploring normative, instrumental and substantive issues

Beginning with the basic question of whether the three theoretical imperatives can be found within the data set, the answer is in the affirmative. Two hundred and seventy-six criteria (out of a total of 310 criteria) reveal, under detailed textual analysis,¹³⁵ either a distinctively normative, instrumental or substantive motivation in the way it was defined. This accounts for approximately 89% of all the criteria defined across the MCM interviews. Summary figures for the two countries are presented in Table 8.1, while summary data of the number of criteria per issue for the five initial perspectives defined in Chapter 7 are presented in Table 8.2. A few comments on how the issues are comprised according to the empirical criteria are then given.

¹³⁵ As discussed in the methodology chapter, detailed textual analysis allows us to make deductions which arise from qualitative analysis of both the content of the criteria and the way it was evaluated under each option.

Table 8.1 Overall criteria matches for UK and US stakeholder perspectives¹³⁶

Criteria Type	Criteria of this type among 147 total criteria defined by a total of 27 UK participants?	Criteria of this type among 163 total criteria defined by a total of 30 US participants?	Criteria of this type among 310 total criteria defined by a total of 57 US and UK participants
Normative	51 criteria defined by 21 participants Mean weighting: 34%	49 criteria defined by 28 participants Mean weighting: 30%	100 criteria defined by 49 participants Mean weighting: 32%
Instrumental	71 criteria defined by 24 participants Mean weighting: 50%	90 criteria defined by 30 participants Mean weighting: 55%	161 criteria defined by 54 participants Mean weighting: 52%
Substantive ¹³⁷	9 criteria defined by 7 participants Mean weighting: 7%	6 criteria defined by 5 participants Mean weighting: 4%	15 criteria defined by 12 participants Mean weighting: 5%
No match or overlapping	16 criteria Mean weighting: 9%	18 criteria Mean weighting: 10%	34 criteria Mean weighting: 11%

Table 8.2: Criteria matches for principal stakeholder groupings

Criteria type	Advocates (12 participants)	Bioethicists (9 participants)	Industry & Professional (12 participants)	Policy-makers & Regulators (12 participants)	Scientists (Labs) (12 participants)	Totals (% of total criteria)
Normative	28 criteria defined by 11 participants Mean weighting: 45%	20 criteria defined by 8 participants Mean weighting: 39%	14 criteria defined by 9 participants Mean weighting: 21%	18 criteria defined by 10 participants Mean weighting: 29%	20 criteria defined by 11 participants Mean weighting: 28%	100 (32%)
Instrumental	26 criteria defined by 10 participants Mean weighting: 39%	22 criteria defined by 9 participants Mean weighting: 45%	43 criteria defined by 12 participants Mean weighting: 69%	38 criteria defined by 12 participants Mean weighting: 58%	32 criteria defined by 11 participants Mean weighting: 49%	161 (52%)
Substantive	4 criteria defined by 3 participants Mean weighting: 7%	5 criteria defined by 4 participants Mean weighting: 11%	1 criteria defined by 1 participant Mean weighting: 1%	2 criteria defined by 2 participants Mean weighting: 3%	3 criteria defined by 2 participants Mean weighting: 6%	15 (5%)
No match or overlapping	6 criteria Mean weighting: 8%	3 criteria Mean weighting: 5%	7 criteria Mean weighting: 8%	7 criteria Mean weighting: 9%	11 criteria Mean weighting: 17%	34 (11%)
Totals	64 criteria	50 criteria	65 criteria	65 criteria	66 criteria	310 (100%)

¹³⁶ Some of the mean weightings in the following two tables do not add up to 100 for a methodological reason. Six participants chose to define a criterion for their MCM interview they thought was important, but they left it unevaluated against the options, either for reasons of time or because they struggled to interpret how it would be evaluated against the options (intellectual property is one example as it was not addressed in the option definitions and participants felt uncomfortable making assumptions). However, they did want to weight the criterion. These ‘partially’ evaluated criteria thus affect the weightings, but not the option rankings. As pointed out in the methodology chapter, they have not figured in much of the analysis since they do not impact on the rankings, but there is a small, residual effect on the weightings, which is why the phenomenon is observed here.

¹³⁷ The average weightings displayed in this row are reflective of the average weightings across the whole perspective, not just those who defined a criterion within this issue. This means that the relative importance to the whole perspective is low, as seen in the table, but for those individuals defining a criterion within this issue, the relative importance was much higher. The average weightings for these individuals is thus, 23% for UK stakeholders and 21% for US stakeholders.

Beginning with normative issues, Stirling (2008) argues that normative views can take various forms, for instance highlighting democratic principles in participatory deliberative processes (Pellizzonni, 2003), or ‘value-free analysis’ in expert analytic procedures. For the purpose of the present analysis, criteria which highlight evidence-based decision-making, or democratic ideals such as openness, representativeness and transparency were all identified as indicating an underlying normative imperative. Among these, two distinct normative emphases were identified, relating either to the nature of deliberations or to the legitimacy of the deliberative process. The following examples are illustrative of the range of meanings:

Public policy should be based on testable knowledge. We must have evidence-based development of public policy (US bioethicist 4, #C279).

Presence of public involvement as an input to governance. It has to be transparent, interactive between the public and government. This interaction goes both ways, if the public have an opinion it should be considered by government (US patient advocate 5, #C303).

It's about the obligation on the part of government to enable input from as many diverse sources as possible and to give it fair consideration (US scientist 3, #C196)

While the first quote reveals a way to secure legitimacy in governance decisions, the second two reflect normatively-grounded beliefs about how deliberative activities should be conducted, regardless of the ends they might lead to. The middle example is particularly interesting in that it seems to express both values of legitimacy and deliberative purpose. If public input is an ‘obligation’ of government, one can infer that if it does not happen, government is failing in its obligation to citizens and, thus, loses legitimacy.

Instrumental imperatives, by contrast, focus on outcomes (Pellizzonni, 2001). These were seen in criteria that discussed education initiatives aimed at public understanding, efforts to foster public trust, or the encouragement of specific policy climates for technological development. Within these, two main types of instrumental issues are identifiable. The first is about how good governance helps facilitate advances in the science, while the second reveals an instrumental desire to achieve public trust through good governance, particularly as a means to further the autonomy of the research system. For example, one criterion about ‘public input’ seemed at first to address normative issues, but actually was defined and used in an instrumental way to

reflect the desire that particular ends were achieved out of such ‘public’ governance.¹³⁸ The following examples represent both types of instrumental criteria identified, the first about advancing the science and the second about public trust as a means to this (implicit) end.

Good governance facilitates responsible scientific discovery in the area of stem cell research (UK bioethicist 3, #C7).

[Governance] has to engage with the general public in order to avoid mistrust. Represent all opinions, not to edit what gets presented at the end (UK professional executive 4, #C331).

Fifty-four of the 57 participants identified at least one criterion of this instrumental type, indicating it was a universally expressed imperative within all perspectives.

Finally, substantive issues were identified based on whether criteria expressed a desire to achieve better ends out of socially-mediated appraisal processes. These referred to ideas such as how good governance could, alternatively, ‘maximise consensual social benefits’ (UK scientist 3, C#193), aid in the application of ‘social values to innovation’ (US Bioethicist 4, #C280), or ensure science is ‘driven by a *societal* need for medical advances’ (US patient advocate 1, C#252). There were only 15 criteria defined by 12 participants across both national settings that satisfied the requirements of identification as a substantive issue.

Though the majority of the criteria were found to reveal one of the three types of imperatives, some did not reveal any particularly strong connotations of a normative, instrumental or substantive nature, or were sufficiently ambiguous (or ‘hybrid’) that no attribution could be made. Of the former group, the criteria were deemed to be more ‘neutral’ in character. This relative neutrality was often difficult to determine. All criteria, to a certain extent, are motivated by the participant’s desire to reflect upon what they consider to be the most important elements of good governance for hESC research. In the widest possible interpretation, then, all criteria have some underlying motivation. These motivations reflect individual values about good governance and socio-political processes, as well as specific ends or outcomes that a governance framework should aid in realising.

¹³⁸ Such criteria about public trust might legitimately be identified as substantive as mutual trust between different sectors of society, governments, publics, scientists and so on, could in itself be a positive quality based on consensual social values. However, what makes these criteria more instrumental is that trust is presented not as a mutual public value, but as something needed because of a public fearful of science and associated institutions. Trust, then, is a means to the privately held, and implicitly expressed, end of advancing science.

The important point here, though, is whether this motivation was akin to those identified in the literature on normative, instrumental and substantive imperatives in policy appraisal or public engagement activities. The crucial question that was asked, then, was whether the motivations could first be distinguished with respect to individual criterion and, second, what the motivation behind each criterion's definition and use in the context of an MCM appraisal exercise might be. For example, Stirling points out that normative imperatives are often associated with particular features of the *process* of appraisal, itself, whereas instrumental and substantive ones are focussed on the *outcomes* (Stirling, 2004, 2006, 2008).¹³⁹ As initially discussed in Chapter 3, in this way Stirling is critically building on Pellizzoni's distinctions of participant engagement along such 'process' or 'outcome' lines (Pellizzoni, 2001, 2003, 2004). While developing the notion that process-based features relate to normative democratic motivations for engagement, Stirling argues that a singular outcome-based conception is insufficient because outcome-based norms can reflect both privately held and publicly held views. While theoretically interesting, all of these distinctions can be empirically difficult to disentangle.

In fact, we find that some criteria that are ostensibly about an aspect of an appraisal process, are actually used to illustrate how an instrumental, outcome-based goal, can be achieved. For example, in discussing how expert advisory bodies should be comprised, an ostensibly process-oriented feature of decision-making, one US participant commented there should be no clergy or religious views represented on expert bodies. This, she believed, could result in governance decisions that were not based on scientific facts and could harm the advancement of science (US professional body 5, #C229). The motivation revealed, then, was actually rather instrumental. This example shows the importance of detailed analysis of both the definition of criteria, as well as their use in option evaluation, before assessments of normative, instrumental or substantive relevance are made.

Moreover, it reveals important implications for the theoretical ideas themselves. In particular, it may expose crucial limits to the extent to which clear distinctions along axes of processes versus outcomes, or indeed normative versus instrumental versus substantive, are identifiable in actual stakeholder appraisals. In the discussion above we have begun to explore the latter set of these axes, and further comments are made in

¹³⁹ See also the discussion in Pellizzoni (2001, 2003). As pointed out in Chapter 3, Stirling's aim is to critically evaluate the process and outcome-based divide, claiming it is not sufficient and that further delineations can be made (i.e. instrumental vs. substantive).

Section 8.2.4 on the distinctions within process- versus outcome-based criteria. Our initial exploration has highlighted that many shades of grey exist in the motivations of stakeholders in appraisal processes. This is first seen in the numbers of ‘unmatched’ criteria that were ambiguous as to a particular motivation along normative, instrumental or substantive lines. It is also seen in the complexities in distinguishing motivations underlying the criteria definition and use in assessment. In reality, it seems there are closely constructed, reflexive and complex relationships between the way stakeholders think they approach appraisal, and the way they act when undertaking it. That is, there seem to be recursively nested interdependencies among the three rationales that are especially evident when real-world appraisals are conducted. For example, normative democratic rationales ostensibly about ‘good’ processes of governance, may also be conditioned by substantive motivations about the consensual social values such processes should lead to. These conceptual, and empirically-based, contributions are further developed in Sections 8.2.4 and 8.2.5.

8.2.3 Option performance under normative, instrumental and substantive issues

Having established that the motivations under examination can be distinguished in respect of individual criterion, we now move to the second question asked at the beginning of this section: do differences exist in option performance based on normative, instrumental or substantive motivations in the criteria? The two figures below show the performance rankings of the governance options under each issue for UK- and US-based participants.

Figure 8.1: Rankings under UK-based perspectives for normative, instrumental and substantive criteria

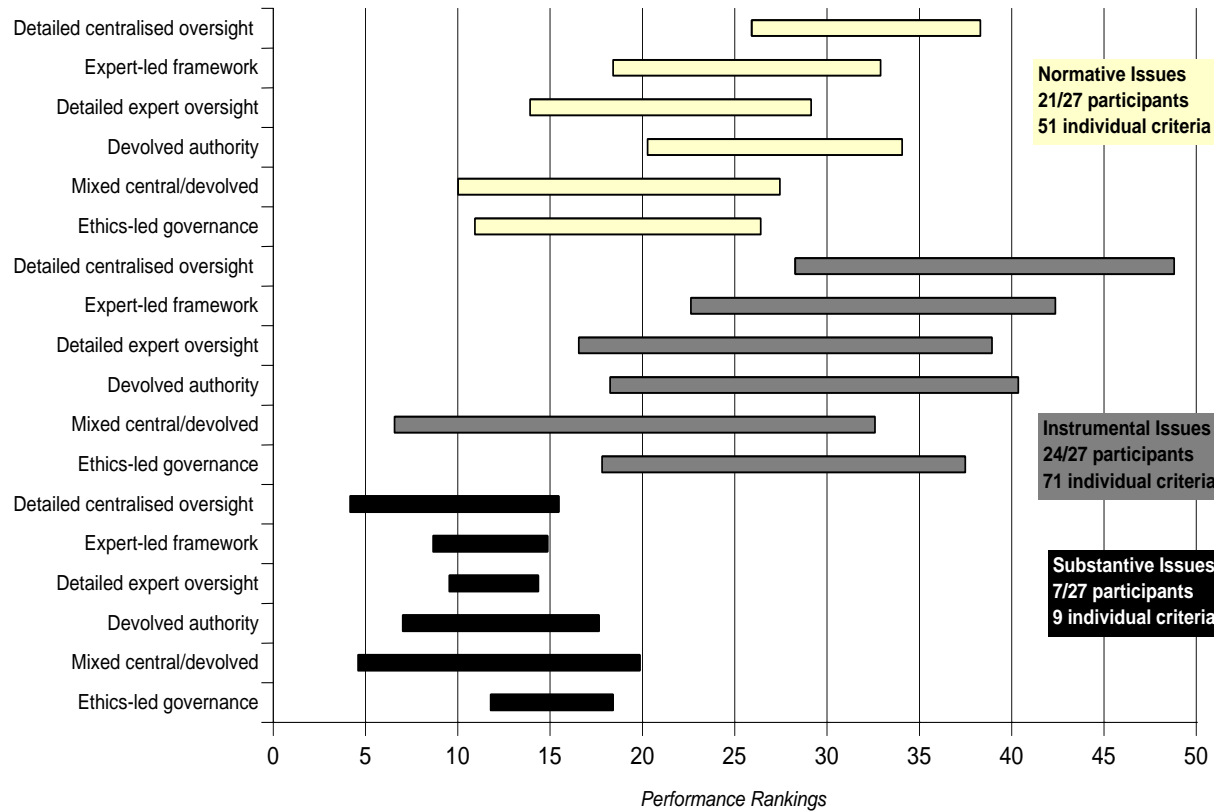
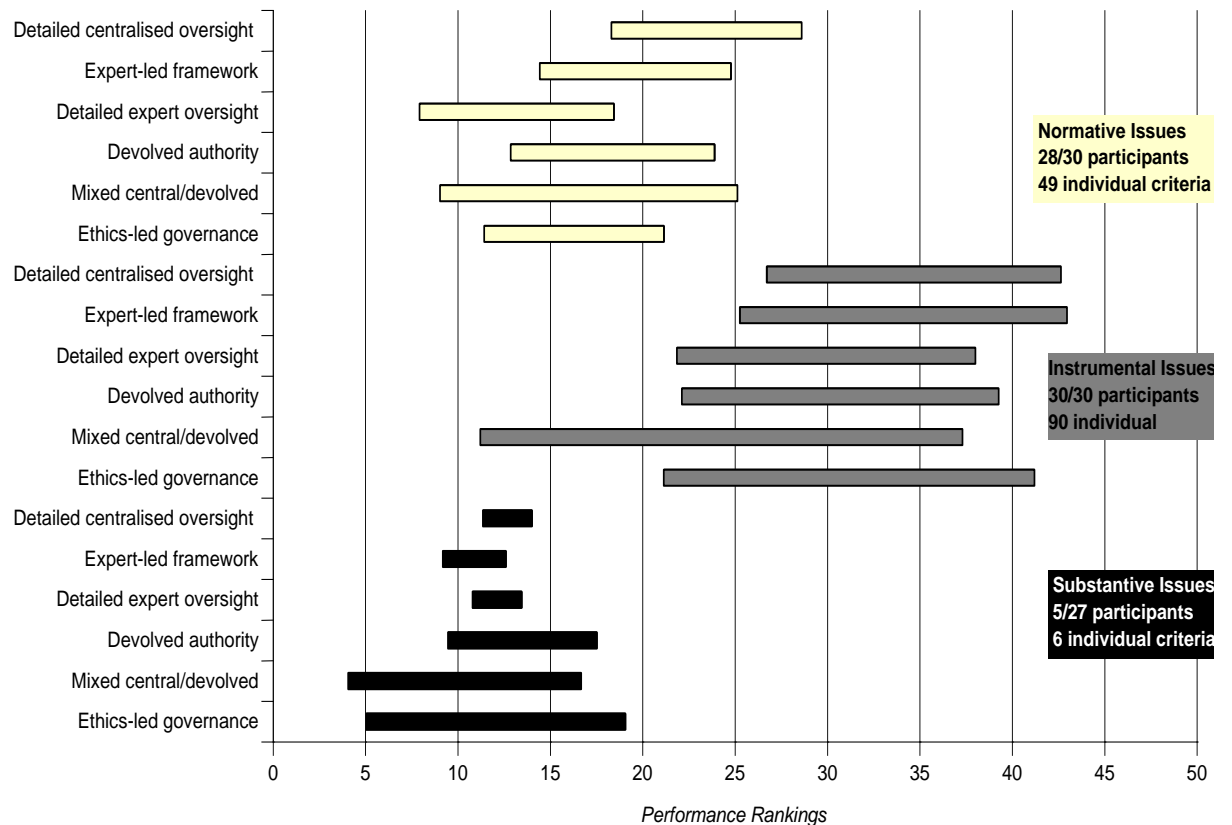


Figure 8.2. Rankings under US-based perspectives for normative, instrumental and substantive criteria



As can be seen from the figures above, differences in rankings by UK and US stakeholders do emerge, both across the issues and between the national perspectives. This seems to offer an initial indication that different patterns exist in the relative prominence of normative, instrumental and substantive criteria. These patterns may contribute to our understanding of differences in the ways in which national perspectives on good governance are characterised. To this end, some features of the patterns should be pointed out.

First, the reader will have noted earlier and can see here, the low proportion of substantive issues within each perspective. This diminishes confidence in conclusions concerning ranking patterns under this issue. However, the point is interesting in itself, because it suggests that substantive aims behind the definition of good governance are either rare, harder to identify, or less consciously acknowledged among participants. Despite this, we still see a remarkable similarity between the ranking patterns for substantive criteria across UK and US stakeholder perspectives. This suggests we might still identify common explanations, for example, a greater potential for fulfilment of substantive issues among options with a strongly decentralised component. Such a decentralised environment may open up access to engagement activities around various governance issues and provide more transparent and accessible opportunities to public deliberation in controversial areas of science policy. Indeed, conclusions of a similar nature were drawn by a research team in the US after conducting a national consensus conference on the issue of nanotechnology (Philbrick and Barandiaran, 2009).

Comparing the rankings for each issue within the UK national perspectives in Figure 8.1, we see that the ranking patterns for normative and instrumental criteria are fairly similar. With some caveats,¹⁴⁰ these relatively similar rankings seem to indicate a particularly close relationship between normative and instrumental motivations. On the other hand, looking at US national perspectives in Figure 8.2, we see a ranking pattern for the two motivations that is more noticeably different than is the case for the UK. Not only are there differences in option performance, but US stakeholders identify almost twice as many instrumental criteria as normative ones. This would seem to indicate that instrumental framings of perspectives on good governance are more prominent among

¹⁴⁰ The most noticeable difference is the reversal in relative performance rankings of the mixed central/devolved option and of the ethics-led option between the two issues normative and instrumental.

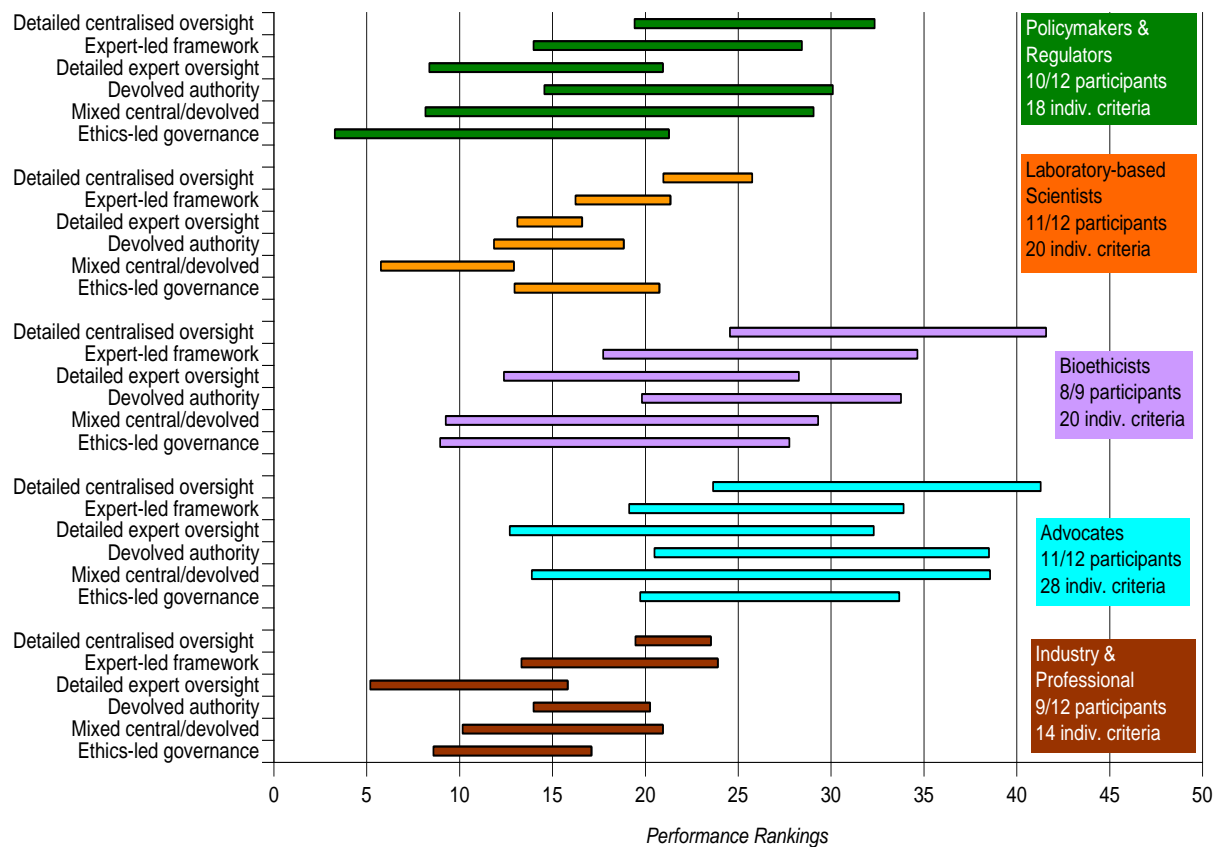
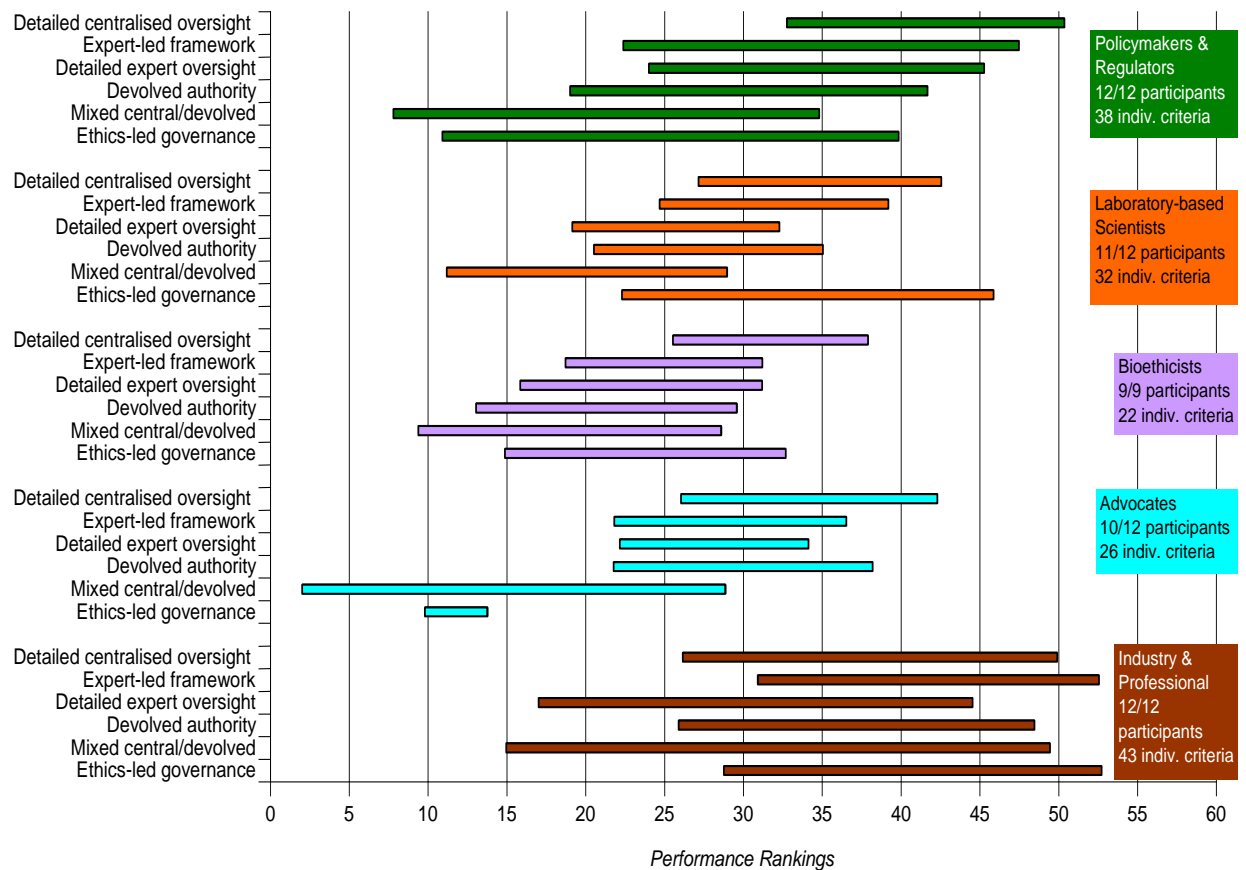
US- than UK-based participants. We can directly test this by looking at the relative importance assigned to the criteria by the individuals themselves.

Analysis of the average weightings of the different criteria groupings, as summarised in Tables 8.1 and 8.2 above, shows this not to be the case. The mean weightings of instrumental criteria are actually rather similar for UK and US perspectives: 50% (UK) as compared with 55% (US). Thus, we might conclude that the two-fold difference is not the result of a greater importance assigned to instrumental criteria amongst US perspectives. It is instead indicative of a more nuanced distinguishing between different means through which desired (and instrumentally framed) ends of good governance are realised. This may be explained by the more complicated governance framework present in the US and, thus, more nuanced articulations of good governance prevail.

Further to this, we see in the US rankings that the expert-led framework, ethics-led governance and detailed centralised oversight options all performed best under instrumental criteria. This seems to highlight one of the tensions discussed in previous chapters about the desire among US-based participants for scientific autonomy, on the one hand, but also stability and harmonised policies, on the other hand. It also reinforces the argument about more nuanced descriptions of instrumental criteria of good governance. Thus, while the expert-led and ethics-led options feature more ‘decentralised’ and ‘hands-off’ approaches to oversight and may be seen as better at fulfilling this perspective, the detailed centralised oversight option may be more able to provide stability if the overarching regulatory framework is permissive.

When considered across multiple types of stakeholder groups, additional patterns are revealed in option performance and perspectives on good governance under normative and instrumental issues. Table 8.2 (above) summarised the criteria matches for each issue by perspective. Those data suggest that there are (at least superficially), some distinguishable patterns across the stakeholder groups. Within these, advocates and bioethicists have almost equal numbers of normative, instrumental and substantive criteria, whereas the other three perspectives have double to three times as many instrumental criteria as normative ones. Figures 8.3 and 8.4 below present the performance rankings for the five stakeholder perspectives being analysed under normative and instrumental issues, respectively.¹⁴¹

¹⁴¹ For the reasons discussed above about low numbers of criteria and, therefore, lower confidence in the findings, ranking patterns for substantive issues are not presented here, but can be seen in Annex K.

Figure 8.3: Rankings under stakeholder perspectives under normative criteria**Figure 8.4: Rankings under stakeholder perspectives under instrumental issues**

As with the aggregated UK and US perspectives, patterns also emerge from comparison of the rankings obtained under disaggregated stakeholder perspectives on normative and instrumental criteria. Brief comments will be made here concerning possibly salient features for the remaining discussions. Beginning with normative criteria, we can see that ranking patterns are rather similar across the perspectives, with any ordinal variations being too small to interpret safely. However, it is the case that these similarities are most apparent in the assessments of policy-makers and regulators on the one hand and the bioethicists on the other. This suggests that these two groups share relatively similar perspectives about the normative democratic values that characterise good governance. Qualitative analysis does find this to be the case, although policy-makers and regulators tend to focus slightly more on normative aspects which relate to legitimacy as a feature of governance, while bioethicists focus on normative features of deliberation processes like openness, representativeness and ‘real’ public discourse (#C39, US Bioethicist 3). However, despite the similarities, there are differences in relative importance assigned to the criteria. Bioethicists having a mean weighting of 39% as compared with 29% for policy-makers and regulators. Such a subtle difference in expression of importance may reflect upon more deep-seated imperatives for good governance which do not otherwise come to the fore. However, the implications of the fact that similar ranking patterns of option performance still exist is intriguing. This point is taken up in much greater detail in Section 8.4 of this chapter.

Looking across all perspectives, under normative criteria we see a common feature of the detailed centralised oversight option performing best under optimistic assessments. However there remain significant variations in the extent to which it is the highest ranking, its relationship with other options and associated degrees of uncertainty. We might tentatively say, though, that this option displays the highest potential to fulfil normative imperatives.

This is not the case, though, under instrumental criteria. Here, the detailed centralised oversight option is less frequently the highest performing option. Moreover, when this is the case, it is (on average) by a notably smaller increment than under normative issues. This suggests that, when evaluating criteria displaying instrumental motivations, there is a greater variability in the types of options and associated conditions for positive performance. Since instrumental criteria are more outcome-based, it may be the case that participants find these types of considerations more

amenable to change, whereas normative, process-based motivations are ingrained within a system.

In addition to the observations about ranking patterns, we do see that, subject to the same caveats expressed in the analysis of UK and US perspectives as a whole, some individual stakeholder groups (policy-makers and regulators, industry and professional executives and – to a lesser extent – laboratory-based scientists), all seem to display greater tendencies to articulate underlying instrumental (more than normative) rationales in their motivations for governance appraisal. In other words, it is among these perspectives that instrumental imperatives feature more prominently in terms of numbers of criteria defined. These criteria span instrumental motivations which reveal imperatives to advance the science (about two-thirds), and to foster public trust, (about one-third). When considered with the qualitative content of the interviews, this similarity suggests that a key driver of an instrumental framing as observed here is the need to engage or work with the public in order to gain trust so that one's 'job' – be it crafting policy, developing hESC technologies, or conducting research – can continue.

When we look at the relative importance of the different types of criteria, though, we find a contrast to that of the UK and US-based analysis. There, the greater number of instrumentally framed criteria amongst US stakeholders did not equate with a greater prominence given to them. However, as shown in Table 8.2, the mean weightings of each criteria group reveal that relative importance is greater for instrumental criteria in the case of policy-makers and regulators, industry and professional body executives, and laboratory-based scientists. In these cases, then, the greater number of instrumental criteria also corresponds to a greater prominence, as indicated by relative importance, of instrumental motivations behind articulations of good governance.

Having now established that normative, instrumental and substantive imperatives for appraisal are, indeed, a meaningful way of partitioning the MCM criteria and, moreover, that differences in option performance can be distinguished depending on the different imperatives, we will now turn to conceptual points about the theoretical ideas, themselves. The next section considers distinctions in option performance based on outcome or process-based criteria and, after discussing the initial findings of such distinctions, compares these to the findings under normative, instrumental and substantive imperatives just described.

8.2.4 Comparing process and outcome characterisations

In Chapter 5, the analysis of UK and US policy documents revealed differences of prominence between *process-* and *outcome-based* characterisations of policy approaches. This, and discussion in preceding sections, suggests that it may be fruitful to undertake further analysis of the MCM findings under these issues. This is all the more so, given the comments at the end of Section 8.2.2 about the difficulties encountered in identifying whether criteria were a) process or outcome-based, b) normative or instrumental/substantive, c) if outcome-based whether they were instrumental or substantive in nature, or d) ambiguously spanning multiple categories.

In order to test this point, we need to consider the MCM findings in a different way to that discussed so far. If we define outcome-based and process-based issues¹⁴², we can then analyse the rankings and criteria assessments and compare them with the analyses of normative, instrumental and substantive criteria. In addition to enhancing our understanding of the MCM findings, such consideration will allow us to determine whether the empirical findings support, contradict or critically elaborate on the theoretical literature reviewed above. The two issues used for the analysis here are defined as:

Process-based: Criteria in this issue are those that relate to features of the process of governance. Outcomes may be referenced implicitly or explicitly, but the focus of the criteria and option assessments is on how the process of governance is characterised.

Outcome-based: Criteria in this issue are defined in terms of the outcomes good governance would achieve. The emphasis is on particular outcomes, with any references to the way in which it is achieved being secondary considerations.

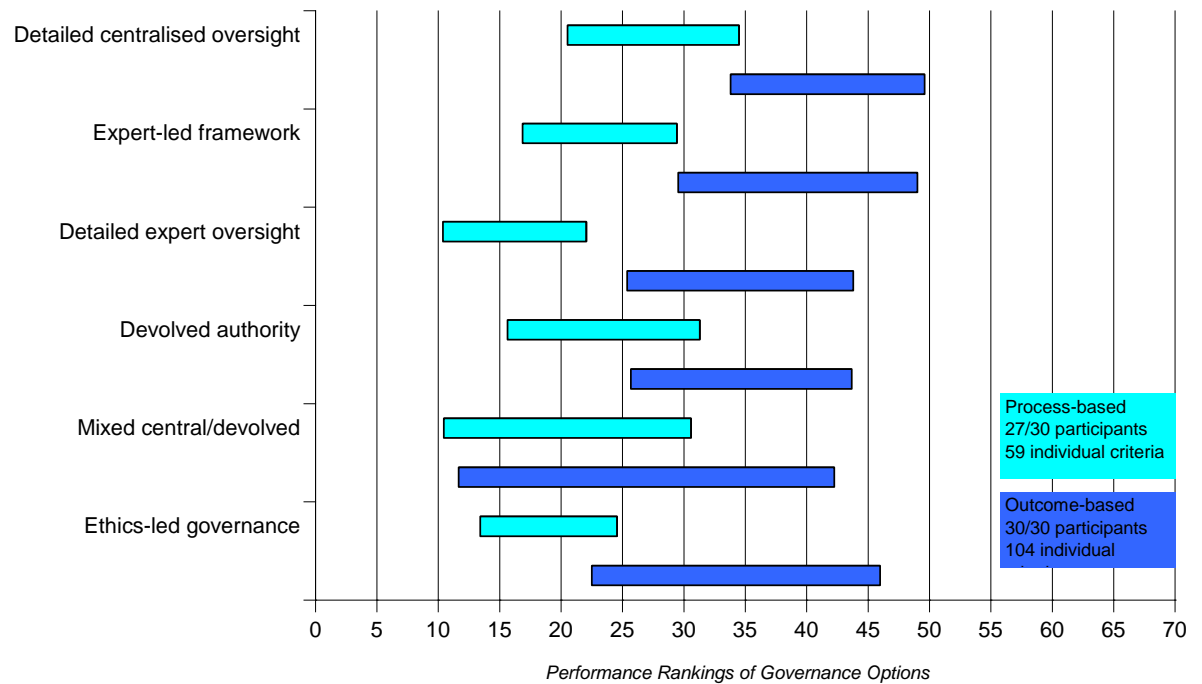
Analysis of this issue below shows that differences in quantitative and qualitative patterns of process-based and outcome-based criteria are visible between and within¹⁴³ the perspectives of US and UK stakeholders and the five stakeholder groups discussed in Chapter 7. Figures 8.5 and 8.6 below show the rankings under UK and US perspectives for the two issues ‘process-based’ and ‘outcome-based’.¹⁴⁴

¹⁴² The term ‘issues’ is used here in the MCM analysis sense of a group of criteria.

¹⁴³ ‘Between’ means that differences can be seen in the definition and use of the two types of issues when compared between the two countries, while ‘within’ means that differences in the definition and use of process-based and outcome-based issues can be seen when compared within each country.

¹⁴⁴ Performance ranking charts directly comparing UK and US perspectives can be found in Annex K. Performance ranking charts directly comparing the five stakeholder groups can be found in Annex K.

Figure 8.5. Rankings under US perspectives for ‘process-’ and ‘outcome-based’ criteria



In the figure above, we can see somewhat distinct ranking patterns under each issue, indicating significant contrasts in the constituting and application of process-based and outcome-based criteria¹⁴⁵. First, US stakeholders identify almost twice as many individual criteria for outcome-based as process-based issues. This prominence is supported by an average weighting of these criteria that is higher by more than a third: process-based criteria have an average weight of 36%, whereas outcome-based criteria have a mean weighting of 63%. This seems to suggest greater concern under US perspectives for the outcomes of governance, rather than the ways in which these occur.

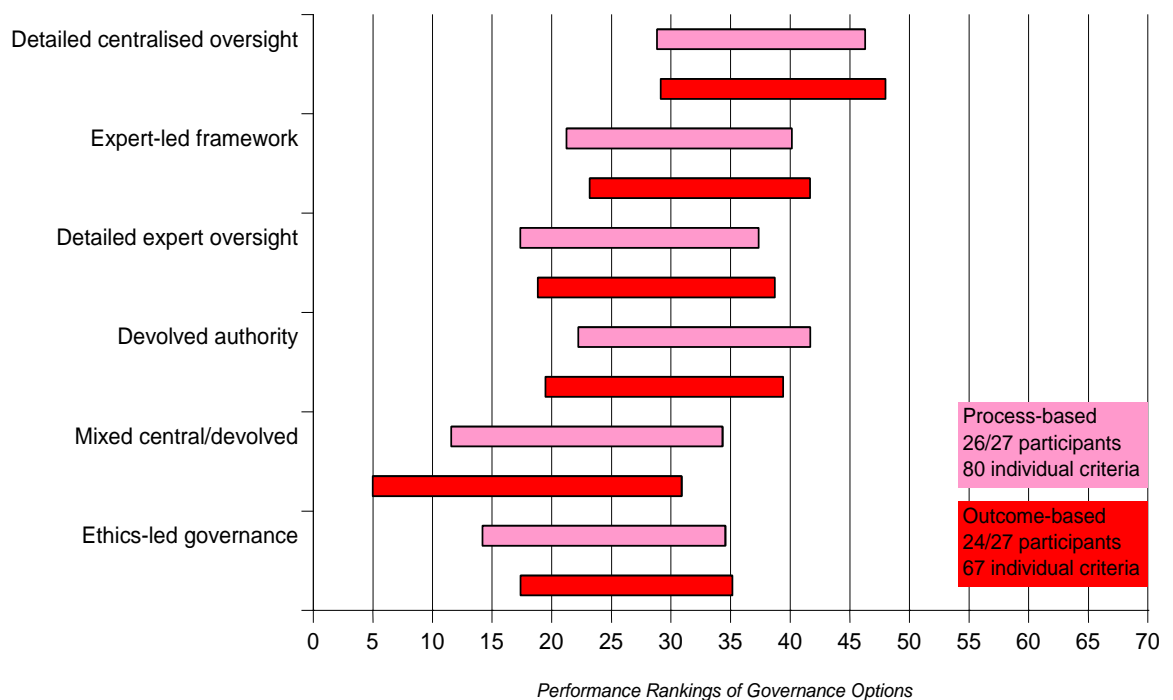
The contrasting ranking patterns noted above arise from a number of discernible distinctions. There is more variation in rankings under process issues, with outcome-based issues displaying an especially pronounced similarity across all options at the optimistic ends of the ranking intervals. This suggests a view that all governance options are in principle capable of achieving similarly high performance, but that there exists greater scope for variation when considering more pessimistic conditions. The rankings also reflect the contrast discussed in the previous section concerning normative and instrumental criteria, showing the two categories to be highly coincident¹⁴⁶.

¹⁴⁵ This is indicated by the different ranking patterns and numbers of individual criteria within the issue.

¹⁴⁶ As we have discussed previously, given the relatively low profile of substantive issues we can be all the more confident that the coincident findings are most pronounced between process/outcome and normative/instrumental categories of criteria, respectively.

What is intriguing in the case of this process/outcome comparison, however, is that a strongly contrasting pattern emerges when attention turns to UK perspectives. Figure 8.6 below compares the ranking patterns under UK perspectives. Here, there are much greater similarities between rankings obtained under process and outcome criteria than are evident in the US. This suggests systematic differences in the way US and UK participants are characterising and defining elements of good governance under this theme. Where this degree of contrast arises, some confidence is gained that individual patterns are not simple artefacts of the method or option definitions. Moreover, these observations echo those from the analysis of the policy literature. We recall from the discussions in Chapter 5¹⁴⁷ that similarities were found between Vogel's analysis of UK and US regulatory strategies (1986) and the analysis in this thesis of the hESC policy documents. Both suggest a greater emphasis on processes, or 'consensus-seeking' (Vogel, 1986, p. 269) in the UK approach, as opposed to a more outcome-oriented strategy of the increasingly 'pluralist' and 'interest-based' (Ibid, p. 278) US regulatory environment. Taken together, these policy document- and empirically-based analytical findings suggest an interesting and potentially significant general contrast between stakeholder perspectives on good governance in the US and UK.

Figure 8.6. Rankings under UK perspectives for 'process-' and 'outcome-based' criteria



¹⁴⁷ See the discussion in Section 5.5, and in particular, p. 116.

As the figure shows, the relatively tight associations in the UK case between rankings under these criteria, suggests a greater inter-linkage, or overlap, in the UK between notions of process and associated outcomes of good governance. This is corroborated both in the relatively equal mean weightings given to each set of criteria (52% for process criteria and 48% for outcome criteria), but also in the qualitative evidence from interviews. In the case of UK participants, we did indeed find process and outcome-based issues more integrated, with the theoretical and analytical distinctions blurred in several of MCM appraisals. For example, the following comment was made by a UK patient advocate in assessing the performance of the detailed centralised oversight option under his criterion ‘instils real trust’:

It’s about the extent to which the system is transparent and challengeable. It has to do with openness of the system and the extent to which public involvement is there and public access to the decision-making process (UK patient advocate 5, #A1783).

This criterion is about an outcome of governance decisions, that of fostering public trust. However, the assessment focuses on the processes of decision-making through which this trust comes about, showing the two to be closely linked. If we look to the way this criterion was defined, further ambiguities and implications for the motivations behind it arise. The participant says that

trust should not be blind. It should operate in a system where there are mechanisms for looking at the checks and balances, for scrutinising the decisions that are made if you want them to be made, [and] where the ... operating the processes are public and can be endorsed by people (UK patient advocate 5, #C310).

In one sense this criterion could be interpreted as instrumental in the way Stirling defines it (2008). The criterion is about his desire for a system of good governance to act in ways that instilled ‘real trust’. In another sense though, the criterion might be interpreted as being substantive. That is, the interviewee favours public discussion and attention to what ‘trust’ means and collective consideration, or ‘endorsement’ of how it is earned. Complicating the picture even more are the elements of ‘good process’ in democratic governance, and hence more normative framings, that are also conditioning the criteria’s definition and use in evaluation.

Examples of such ambiguity in option assessment and criteria definition further support the conceptual points made at the end of Section 8.2.2 that there are both shades of grey in understanding stakeholder motivations, as well recursively conditioned relationships between the three imperatives in appraisal. This is further evidenced in

another participant's reflections on his process-based criterion 'flexibility' and its evaluation under the devolved authority option:

At the upper level it's to a degree like what we have in the UK, where we have the oversight not as flexible as you might like, but at the local level you might have assistance and more flexibility there... you may actually have influence if something positive is coming out from local level changes (UK patient advocate 3, #A24).

Again, the feature of the governance process being inherently flexible is linked to the outcome of having the science advanced and the impact of change at the national level. Thus, though it is a *process-based* criterion under one analysis, the fact the assessment was concerned with how that process helps to advance science means it was found to reveal more *instrumental* motivations under the other.

At the risk of belabouring the point, these distinctions are also borne out when the ranking patterns under normative/process-based criteria as well as instrumental/outcome-based criteria are compared across the five stakeholder perspectives. We find that the patterns between each grouping are similar, but some variations are apparent within the finer-grain distinctions according to normative and instrumental criteria. We would expect this to be the case on the basis of the heuristic distinctions between normative, instrumental and substantive imperatives and their relative grounding in process- or outcome-based features of governance. The important point, though, is that more fine-grain analysis of key drivers are possible when we look at the normative, instrumental or substantive imperatives, as discussed in earlier sections.

Thus, our conclusions from this discussion are two-fold. First, contrasting perspectives between UK and US stakeholders were found in the way processes of good governance are seen to relate to outcomes of good governance. Second, and more directly related to the theoretical literature being empirically tested, is the observation that in looking at the findings through the analytical lens of normative, instrumental or substantive imperatives versus process or outcome-based characterisations of good governance has *tangible implications* for option performance. Each partitioning illuminates distinct features of perspectives on good governance, with associated framings and motivations underpinning governance strategies coming to the fore. However, the quantitative and qualitative implications highlighted in the analysis reveal possible empirical limitations to the theoretically grounded ideas.

8.2.5 Discussion

A growing area of theoretical literature explores the normative, instrumental and substantive motivations that might lie behind processes of technology appraisal. This literature argues that a focus on understanding the cross-cutting dynamics within both participation and analytic appraisal processes, as opposed to focussing on the dichotomies between them, might prove more useful in the opening up and “empowering of human agency in the deliberate social choice of technological futures” (Stirling, 2008, p. 286). Thus, identifying the underlying rationales and motivations for appraisal as they apply to both the participatory and analytic forms can enable a deeper understanding of the reasons for, or conditions under which, the ‘opening up’ or ‘closing down’ of science and technology choice in wider policy discourses¹⁴⁸ should, or could, occur. While these ideas have been explored theoretically, they have not previously been tested empirically.

In applying the theoretical notions to the empirically generated set of MCM criteria, we find the ideas to be substantiated. A detailed analysis reveals not only evidence of all three sets of motivations within the criteria (although substantive motivations noticeably less so), but different patterns in the performance rankings under each issue emerged for different groupings of stakeholders. However, often there were overlaps and inter-dependencies in the definition of the criteria, where, for example, process-based norms are invoked in instrumental ways, substantive motivations reveal normative conditions of process, or normative features of democracy are discussed in the context of instrumentally favoured outcomes. Two implications for the theoretical ideas emerge from this finding. First, while normative, instrumental or substantive rationales may be broadly distinguishable as being process and outcome based, this does not always provide a greater level of clarity in distinguishing among more ambiguous motivations and rationales. Process and outcome based distinctions of good governance reveal a different type of contrast between perspectives on good governance than do distinctions based on normative, instrumental and substantive. Second, we have contributed conceptually to theoretical insights in the area of technology governance by showing that, in addition to the implications of process and outcome distinctions, the imperatives themselves are reflexively co-conditioned and mutually constituting in

¹⁴⁸ See the discussions in Section 3.3, in particular p. 52-53.

deep-seated ways. The fact that both of these findings are empirically grounded reinforces the significance of this contribution.

This latter point has practical implications for our understanding of why it is important to explore the drivers of contrasting framings of good governance. The point is to enable understanding of the diverse framings and sensitivities which condition the perspectives on different technology choices or governance strategies which are being considered. Thus, by finding that such underlying rationales and imperatives can be identified in empirical settings, we show specifically how MCM fulfils the requirements of the theoretically-grounded concept of ‘opening up’ technology appraisal.

8.3 Establishing moral and ethical awareness

8.3.1 Introduction

Moral and ethical concerns surrounding hESC research are never far from the centre of policy debates and governance discussions. Certainly in the case of the policy literature analysed in Chapter 5, the moral and ethical language used to discuss the status of the embryo and conduct of the research featured prominently, and even seemed to frame the nature of governance considerations in both the UK and the US settings. The question now becomes one of how the perspectives on good governance with respect to moral and ethical aspects in hESC research are constituted among the different groups of stakeholders interviewed for this research. The analytical MCM issue was defined as follows:

Moral and ethical aspects: *Criteria under this issue address moral and ethical concerns related to hESC research. Many concern both the need for ethical guidance and application of ethical norms to this area of research, as well as the need for ethically-based deliberations to inform decision-making.*

Three distinct types of criteria constitute this issue group: *i*) criteria relating to the *moral* status of the embryo and the implications of using embryos in research; *ii*) criteria about the *ethical* principles that should guide the conduct of hESC research; and *iii*) criteria about the need for *ethical* deliberations to inform these principles and other elements of governance for hESC research. While the former adopts a framing based on the moral values implicated in hESC research, the latter two adopt a framing based on ethical principles.

The distinction is subtle, yet important both theoretically and conceptually. Theoretically, ‘morality’ refers to an individual’s or group’s attempt to “live out in daily

attitudes and actions their vision of the highest good” (Young, 2001, p. 163). According to Young, moral systems are often tied to particular religious traditions or cultural histories. ‘Ethics’, on the other hand, “employs a common or public language in justifying assertions about prescribed or proscribed attitudes and actions” (ibid.). Conceptually, in order to use moral arguments in public debate, Young argues one must use the “neutral language of reason” and “appeal to shared societal values”, thereby shifting the preferred rhetoric of the moral system to a more neutral language of *ethics* (ibid.).

Though a detailed theoretical application of these ideas is beyond the scope of this thesis, the distinction is important to bear in mind. There are important insights to be gained from appreciating both the ‘unquestioned’ distinctions between ‘ethics’ and cultural ‘values’ (Tallacchini, 2006) as well as the more normative implications for policy-making that arise from the non-academic application of ‘ethics’ and ‘morals’. Tallacchini points out one such implication in commenting that

In moving from academic to institutional settings, moral thought has been radically reinvented ... ‘ethics’ has acquired a quite established soft regulatory status consisting in the production of ‘valid ethical knowledge’ that legitimately enters in the legislative process (Tallacchini, 2009, p. 283).

Analysing the empirical findings with an eye to these theoretically grounded distinctions will be a key aim of the following section. In this regard, the analysis below will highlight relevant points that emerge from the qualitative analysis of this issue group across the various perspectives. However, the performance rankings and assessments made by participants will not be presented here.¹⁴⁹ This is partly due to space constraints but is also due to the fact that, in comparison to issues in other themes, the number of criteria within this issue is relatively small. Thus, we are somewhat less confident about the implications of the option rankings, but nonetheless can make meaningful inferences from the qualitative information produced during the interviews.

8.3.2 Moral and ethical aspects of hESC research: stakeholder views

The point about the relative number of moral and ethical criteria defined, and the number of participants defining them, is of interest in itself and is where our analysis begins. The review of the policy literature in Chapter 5 found that while the UK policy literature adopted a consistent, more technical framing of the embryo (observed through

¹⁴⁹ A full set of analytical charts for the different perspectives can be found in Annex K.

coining of the term ‘pre-embryo’), the US policy literature reveals a rather inconsistent framing of the embryo which varies between policy documents. Despite this, in both sets of literatures, the moral status of the embryo was an important component of governance discussions.

The fact this framing is central to the discussions in the policy literature makes it all the more curious that so few participants specifically address it in their interviews: out of 56 moral and ethical criteria across all interviews, only nine criteria (defined by eight individuals) specifically discuss the sensitivities of the use of embryos in hESC research. Seven of these nine criteria are defined by UK participants (amounting to six out of the eight individuals). However, what is even more intriguing, and entirely fitting with the importance given to the moral status of the embryo in the policy literature, is the fact that seven of the eight individuals who did define a criterion about the moral status of the embryo were either policy-makers, or held some position on a government advisory panel. This, combined with the fact that six of the eight participants are from the UK, suggests that reference to the moral status of the embryo is not only a more prominent feature among UK-based participants, but in particular UK-based policy-makers and regulators.

Possible explanations for this finding vary. One explanation might be that for the very fact that the status of the embryo continues to be so contested in US policy-making, US stakeholders, including policy-makers and regulators, steer clear of mentioning it where possible. Even a participant who is generally opposed to hESC research did not explicitly use the term ‘embryo’ in his evaluations, but rather ‘innocent life’. He entitled his criteria as ‘the defence of human life and dignity’ and explained it in the following way:

Government is there to protect against violation of certain rights. Government itself should not violate these rights. So that means we shouldn’t pursue policies that take innocent life on the one hand, or diminish respect for human dignity... It’s a principle of showing regard for what is unique about individual human beings (US bioethicist 5, #C245).

In further support of this explanation, we find more criteria relate to principles for ethical *conduct* of hESC research (as opposed to ethical deliberations) among US-based participants. Thus, it could be that US stakeholders see discussing such issues around the ethical conduct of research as more fruitful, since the moral questions relating to the embryo get bogged down in incompatible moral framings.¹⁵⁰

¹⁵⁰ c.f. Young, 2001 as discussed above.

Given this, we might also expect the types of criteria referring to ethical principles, more generally, to implicitly refer to the fact that this is an area of science rife with moral and social sensitivities. This is, in fact, what we find. Criteria about ethical conduct emphasise the need for, variously, ethically-based ‘frameworks’, ‘oversight’ and ‘guidelines’. This view was particularly prominent among laboratory-based scientists. The acute awareness of the sensitivities of their work seemed to contribute to a clear expression of the importance of thinking through, and *being seen* to think through, the moral and ethical ramifications of conducting hESC research.

Morality comes into play here... Obviously there needs to be sets of rules because some experiments just shouldn’t be done (US scientist 5, #C58).

Society needs to determine what is morally correct for itself, and this can be difficult to achieve. Good governance would be about facilitating these types of discussions throughout society ... listening to society (US scientist 3, #C284).

The latter of these two quotes illustrates the other type of ethically framed criteria, those related to the importance of ethical deliberations. Though the above quote is made by a US scientist, criteria about the importance of ethical deliberations were mentioned more frequently by UK-based participants (at the national level of comparison), as well as by bioethicists and advocates (at the inter-stakeholder level of comparison). These criteria relate to the need to actively consider different social, ethical and moral views when making decisions about hESC research governance. One advocate opposed to hESC research (on the grounds it destroyed human embryos) stated,

Issues like ethics, morality... generally people think a lot of those ideas go together, but it’s about whether it’s right or wrong in itself. How to reach a consensus of what is right or what is wrong is complex and that does involve society as a whole (UK opposition policy 2, #C201).

Another UK-based participant commented that government should “maximise the consensual social benefit.”

What one is trying to achieve, in the end, is to maximise consensual benefit from this sort of endeavour. This entails two potentially conflicting or opposing things. One is that there is a general social interest in improving our general understanding of biology and that has specific connotations about managing nature. All of that is in favour of doing everything [in terms of the science]. Opposing that are certain social and ethical constraints that a society regards as reasonable. [Governance] is about trying to find a reasonable blend and balance of those conflicting objectives (UK scientist 3, #C193).

In many ways, this quote illustrates the issues this thesis is exploring in terms of the governance challenges posed by biomedical technologies like hESCs. The point is, that

governance decisions cannot occur in a vacuum and social and ethically-based concerns must factor into the decision-making process.

The tables below summarise the characterisations of ‘moral and ethical issues in hESC research’ in the corresponding theme of good governance across the stakeholder groups. Table 8.3 displays the main patterns across UK and US stakeholders, as well as in comparison to the relevant national policy literature.

Table 8.3. Summary of patterns under the theme ‘addresses ethical and moral issues in hESC research’

Addresses ethical & moral issues in hESC research		Perspectives from US Policy literature vs. US stakeholders	Perspectives from UK Policy literature vs. UK stakeholders	Perspectives of US stakeholders vs. UK stakeholders
Addresses ethical & moral issues in hESC research	Defines principles of research conduct	Broadly congruent	Slight Divergence	Slight Divergence
	Moral status of the embryo	No clear signal	Slight Convergence	Noticeably divergent

Shading Key

Noticeably divergent: Distinct differences across the two perspectives are clear and readily identifiable
Slightly divergent: Some differences across the two perspectives are clear. Similarities or unclear signals exist.
Slightly convergent: Some similarities across the two perspectives are clear. Differences or unclear signals exist.
Broadly congruent: Similar patterns across the two perspectives are clear and readily identifiable.

Overall there is a slight divergence between US and UK perspectives on good governance within this thematic aspect for principles of research conduct, and stronger divergence with regard to how the moral status of the embryo is addressed. In the UK, the perspectives on good governance that emerge in this area are less to do with the actual conduct of the research and more to do with the ways in which society might come to decide on what those principles of conduct might be. The US perspectives on good governance are shown to centre largely on criteria related to the types of ethical frameworks and guidelines that should be in place in order to ensure that responsible scientific discovery can take place. The findings summarised above seem to offer an explanation for the differences in UK and US perspectives that relates, in part, to the particular policy environments that existed in each country at the time of the interviews.

Table 8.4 summarises the main patterns in the perspectives across the five main stakeholder groups.

Table 8.4: Summary of patterns under the theme ‘encourages ethical and moral awareness for hESC research’

		Policy-makers & Regulators	Scientists (Laboratory)	Bioethicists	Advocates	Industry & Professional
Encourages ethical & moral awareness for hESC research	Principles of research conduct	Enforce ethical compliance	Establish ethical guidelines	Ensure ethical inputs	Balance ethical guidelines and deliberations	Part of business model
	Moral status of the embryo	Respect for social norms (5 criteria)	Respect as scientific resource (1 criterion)	Respect for human dignity (1 criterion) ¹²	Respect for sensitivity (2 criteria) ¹⁵¹	No criteria expressed

Shading Key:

	Indicates a particularly strong signal from the empirical data and emphasis is placed on these areas in the text.
	Indicates a clear signal from the empirical data, but findings are not always central to argument.
	Indicates some individual points from the analysis were of interest, but overall the findings are not central to the argument and, moreover, there was not sufficiently clear signal to merit further analysis.

Here we find that the perspectives of individual stakeholder groups also seem to reflect the particular social and political environment they encounter on a daily basis. Scientists recognise the sensitivities involved with their area of work and the need for ethics to play a role in both shaping and informing oversight. Stakeholders from industry and professional bodies realise that if ethical sensitivity is not a part of their business model, they will lose trust, and therefore, their market. Bioethicists are concerned with broad-based ethical deliberations feeding into the development of ethical oversight, as are advocates of different types. However, some advocates reveal a particularly instrumental motivation in ‘winning’ public support to their side through discussion of ethical principles. Finally, we discussed above how policy-makers and regulators, more so than other perspectives, emphasise the moral questions over protecting the embryo while grappling with how to translate this into a form of ethical compliance that upholds this moral framing in law. We will conclude this section by making further links to the academic literature.

8.3.3 Discussion

The discussions above have shown that distinctions in the framing of ethical and moral perspectives on good governance are evident across various stakeholder perspectives. This is observable in the fact that there are few criteria relating to the

¹⁵¹ These criteria were defined by individuals who also had a formal role in advising policy-makers through their service on expert advisory bodies at national or regional levels.

moral status of the embryo. Those interviewees who do define criteria about the moral implications of hESC research are overwhelmingly those involved in developing, advising or implementing policy. Among the other stakeholders, issues around moral and ethical awareness are framed in terms of the ethical principles that should guide the conduct of hESC research and deliberations about its conduct in wider society. There are several implications of this for wider theory.

In relation to criteria about ethical research conduct we may be observing a more indirect way of speaking about the moral status of the embryo. In attempting to re-frame the question in a way that moves the discussion away from the intractable moral issues and towards the ‘grey’ language of ethics (see the discussion of Young, 2001, as above), it could be that stakeholders are forging new paths forward through otherwise seemingly intractable governance debates.

Theoretical and empirical support for this explanation might be found in a phenomenon known as “absent presences”; a term adopted by Law and observed in a recent public engagement study by Felt and colleagues looking at ethical discussions around genome research (Law, 2004; as cited in, Felt et al., 2009). In Felt et al.’s study, they hypothesise that participants discuss ‘ethical’ issues as social or political in nature. In so doing, they argue participants seemed to be masking, either from themselves or others, the complexities of ethical issues pertinent to the issue of genome research by calling them something else. Thus, it might be that a similar ‘absent presence’ phenomenon is observed here. If this is the case, the lack of criteria specifically addressing the moral status of the embryo does not suggest it is unimportant, but rather it is framed in a different way in order to mask the complexities in the debate, or to enable the debate to move forward.

Under any set of explanations, the empirical finding of such a shift in framing from ‘moral status’ to ‘ethical conduct’ among the majority of the stakeholders is significant. It suggests that those actually advising, crafting or implementing policy are operating within a different frame of reference to that of most stakeholders ‘on the ground’. Moreover, these stakeholders may see an entirely different set of issues as affecting the ‘problems’ of policy-making and governance, more generally, in this area. Considering this in light of the discussion of the policy literature in Chapter 5, we might conclude that the perspectives on good governance extant in formal US and UK policy literatures are also framed by rather different sets of problems than are evident in the perspectives of stakeholders in the respective countries. That is, ethical and moral

elements of good governance in the policy literature may be discussed in less nuanced ways and with less breadth than is articulated by the stakeholders themselves. While this observation could be a result of a limitation in our ability to deeply explore the policy literature to the same extent as an interview discussion allows, the fact that such divergent perspectives are found across the stakeholder perspectives at multiple levels¹⁵² does seem to suggest that there is merit to our claim.

Consequently, we can now say with some confidence that it is not only the policy literature that tends to dwell strongly – and frame the governance discussion in terms of – the *moral questions* of stem cell research, but evidence of this framing is also found among stakeholders who are involved in advising on and crafting policy. This is not to say these issues do not feature at all in other stakeholders’ perspectives on good governance – and indeed may be ‘absent presences’ – but it is the case that the moral and ethical criteria defined by the majority of interviewees tend to emphasise the ethical conduct of hESC research and application of technologies, as well as the ethical deliberations which should inform governance discussions. Therefore, for many interviewees, there seem to be a wider set of concerns under the moral and ethical umbrella than simply the moral status of the embryo. Thus, we might say that, in contrast to the greater use of moral and ethical language to describe governance, and frame good governance, in the policy documents, stakeholders interviewed seem more concerned with wider *socio-political* and *institutional* factors in good governance. This dichotomy links to academic literatures relating to the relationship between ‘ethics’, ‘bioethics’ and policy-making and leads us directly into the topic of the next section: the emergence of bioethics as a new mode of expertise.

8.4 Bioethics as a new mode of expertise?

8.4.1 Introduction

The implications arising from the discussion in the previous section relate to the concerns raised in the academic literature¹⁵³ over the rise of bioethics as a new mode of expertise in biotechnology decision-making. This is seen in many ways, including in the rise of “bioethics forums” (Gutmann and Thompson, 1997), “official bioethics” (Jasanoff, 2005), and “public bioethics” (Kelly, 2003). Many argue that bioethics and its

¹⁵² This is seen in the perspective patterns in Table 8.4.

¹⁵³ See discussion in Chapter 5, p. 122-124.

associated rhetorical strategies has emerged as a new source of legitimacy in government discussions (Brown and Michael, 2002), and has become the preferred language and ‘currency’ for publics and policy-makers, both nationally and internationally, to trade in and negotiate with when developing biomedical technology policies (Salter and Salter, 2007; Gottweis et al., 2009).

In its emergence as a preferred tool for policy-makers (Grove-White, 2001), it is argued that governments seem to be seeking

fresh forms of relationships between science and society – not simply to re-legitimize scientific advice in the eyes of the wider population, but even to help, indirectly, to reconstitute that science in terms which may then be experienced as sensitive and relevant to society as a whole (ibid., p. 467).

Arguments made by Tallacchini (2009) can be interpreted as supporting this statement. She calls attention to the “uneasy” relationship between scientific “facts” and cultural, ethical or moral “values” in today’s “knowledge society” (Wynne et al., 2007). Thus, ethics is invoked by governments in order to promote shared understandings and address feelings of risk and uncertainty which may result from new biotechnologies (Tallacchini, 2006). Similarly, in an extensive review Jasanoff convincingly argues that in response to the challenges faced by advancements in biotechnology, including hESC research, bioethics offers governments the “promise of bringing order and principle to domains previously governed by irrational, emotive and unanalyzed reactions” (Jasanoff, 2005, p. 172). Thus, in much the same way policy-makers looked to technical risk analyses or expert appraisal in previous years when confronted with scientific uncertainty, so they look now to the new institutions of bioethical expertise in order to ‘make sense’ of developments in biotechnology.

Thus, it is with some confidence we can argue that public bioethics bodies have come to represent an “appropriate strategy for engaging public disputes about science in pluralist democracies” (Kelly, 2003, p. 342). As Tallacchini (2009) points out, however, the danger is that rather than meaningfully engaging the public and seeking their pluralist views, the task of discussing ethics is left to experts. Since bioethics experts can, ostensibly, provide “a predominantly secular, rational, and ‘neutral’ discourse, not unlike the law or science itself” (Kelly, 2003, p. 342), bioethical expertise becomes a new domain in which ‘objective facts’ are created, not unlike those of ‘technical’ advisory bodies. The irony is that this objectivity is created in the very ‘subjective’ space that ethical deliberations are intended to explore. This point is important and is drawn out further below.

The problem, then, as pointed out by the authors just reviewed, lies in an unquestioning acceptance of the role of ethics in institutional processes. This is not to say that ethics should be ignored, indeed the participants in this thesis all indicate that ethics *does* need to be considered as part of a system of ‘good governance’, but rather there are important relationships to explore within the perspectives of bioethicists and policy-makers in our empirical analysis. Specifically, we might ask how and in what form does the relationship between the perspectives of policy-makers and regulators and bioethicists take shape, and what are the implications for option performance, or in the ‘real world’, policy-making?

8.4.2 Insights from empirical findings

The empirical findings of this thesis as compared between policy-makers and bioethicists are intriguing, although they may pose more questions than they answer. Overall, we find that there are many points of convergence and synergy in the patterns of performance rankings across the two perspectives. That is, when analysed quantitatively, the ranking patterns between bioethicists and policy-makers and regulators reveal several similarities. This is particularly the case in three areas, all shown in the set of figures below: *i*) the mean aggregate rankings (Figure 8.7); *ii*) under criteria related to ‘advancing the science’ (Figure 8.8); and *iii*) under criteria relating to the ‘qualities of deliberative activities’ (Figure 8.9).

Figure 8.7: Rankings under policy-makers & regulators and bioethicists perspectives

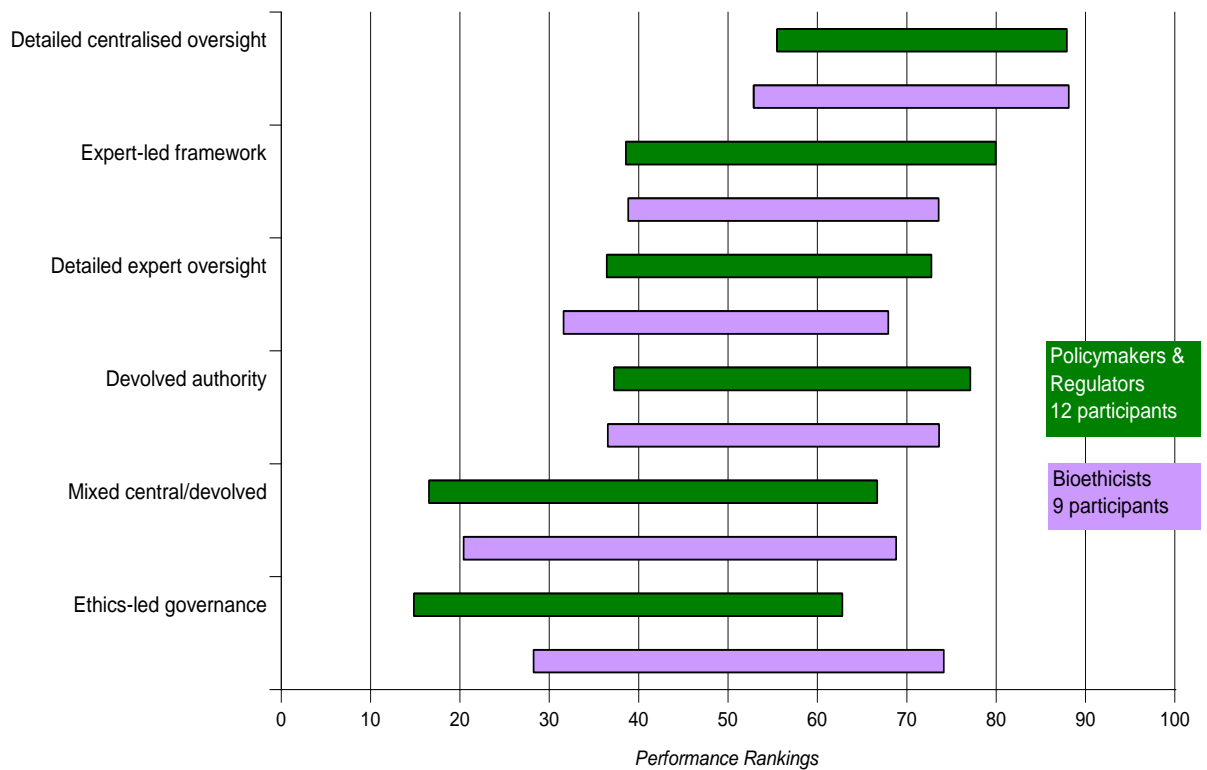


Figure 8.8: Rankings under policy-makers & regulators and bioethicists perspectives under 'advancing the science' criteria

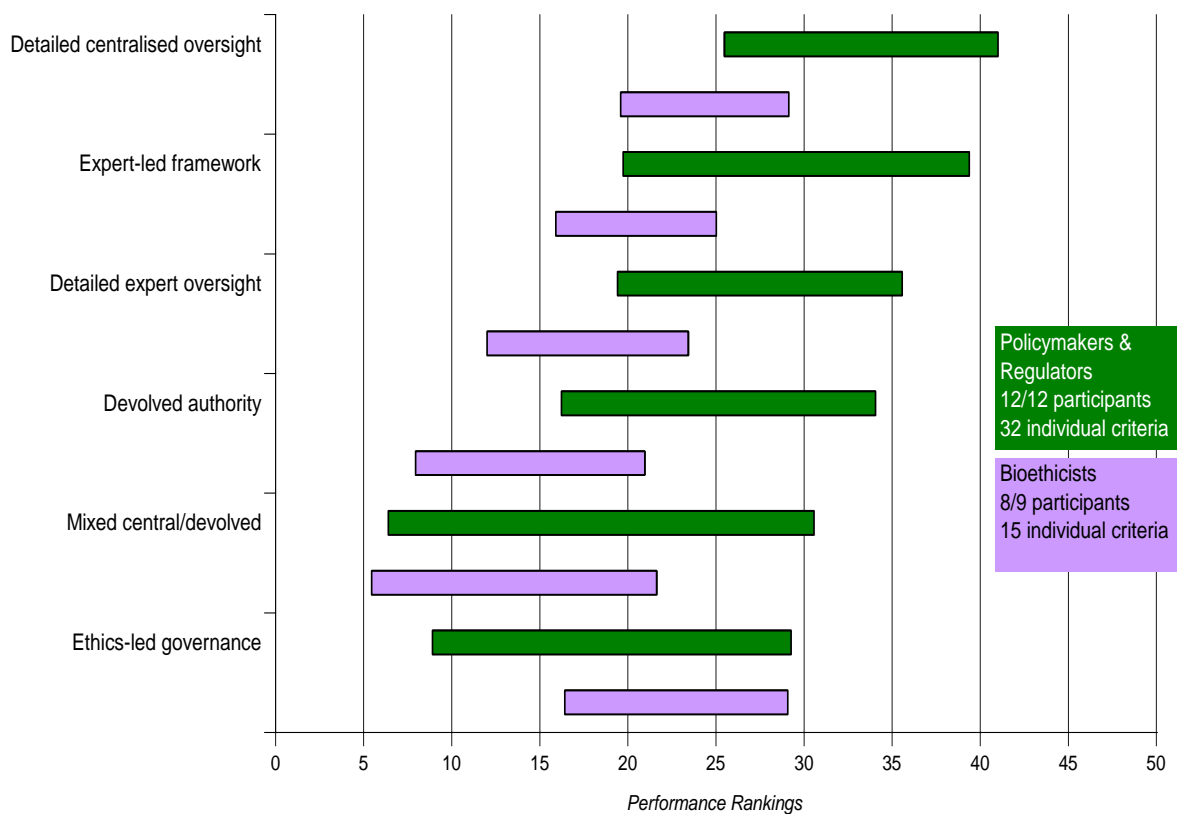
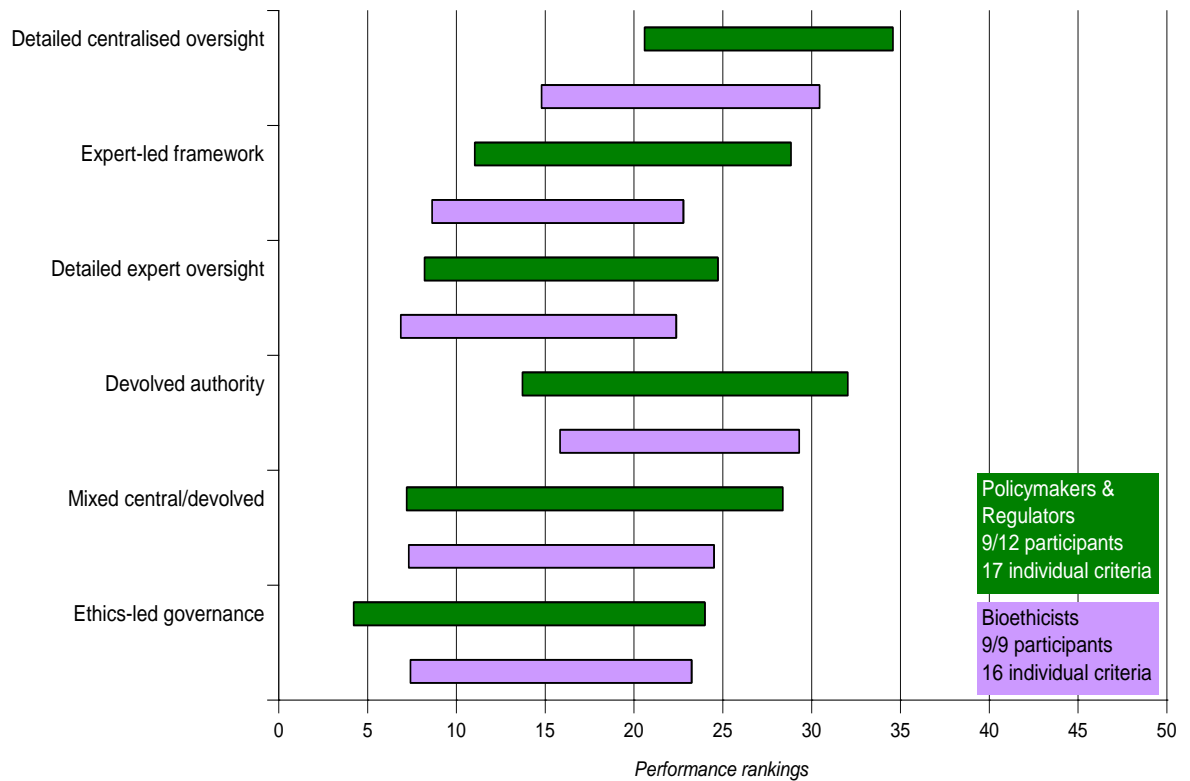


Figure 8.9: Rankings under policy-makers & regulators and bioethicists perspectives under ‘qualities of deliberative activities’ criteria



As we can see from the figures, there are a few exceptions to the similarities and convergence in ranking patterns. A notable one is the ordinal ranking of the ethics-led governance option, where there is a slight variation in the relative patterns across the figures. One might also notice the seeming divergence in rankings under criteria related to advancing the science (Figure 8.10), but on closer examination we see that the ordinal pattern between the two stakeholder groups is similar (despite the lower relative positioning of the rankings for bioethicists). This is due in large part to the fact that fewer criteria comprise the issue for the bioethicist group, but also is a factor of the lower mean weighting assigned to these criteria by bioethicists (30%) as opposed to policy-makers and regulators (48%).

However, despite the convergence in performance rankings, the analysis presented in the previous chapter showed there to be regular and systematic *divergences* in the way perspectives on good governance are expressed, characterised and framed between the two stakeholder groups. In Chapter 7 we found that the perspective of policy-makers and regulators on the issue ‘advances the science’ was framed by a view of the importance of supporting ‘high quality’ science through proportionate regulation

or harmonised policy frameworks. The perspective of bioethicists, in contrast, was characterised by a beneficent framing of the quality of scientific outcomes.

There were differences in the evaluation of the options, indicating some degree of ambiguity¹⁵⁴ was present among the bioethicists, themselves. It was argued this might be attributed to the diverse contexts in which the bioethicists worked. Moreover, though both groups of stakeholders emphasise the role of the public in their discussions of deliberative activities, the perspective of policy-makers and regulators was more focussed on how institutional mechanisms of governance might foster public trust. Bioethicists, conversely, tended to exhibit a greater degree of pragmatism as to role of the public and the need for good governance. That is, there was a feeling that the cultural pluralism inherent in societies needed to be respected and addressed, but there was also a recognition that the policy process needed to move forward. At some point, *good* governance would need to result in the development of policy solutions.

8.4.3 Discussion

The final point made above is worth dwelling on and is where the implications for theory-building emerge. Though all the bioethicists participating in this study had some level of academic training in bioethics, philosophy or other related disciplines, they all worked in different contexts. Some were academics who studied bioethics in the area of hESC research, others were policy advisors to national policy-making bodies, and still others worked for professional medical or industry organisations. Gottweis, *et al.* (2009) point out that national ‘bioethics’ bodies themselves are comprised of individuals from diverse backgrounds, many of whom have no formal training in ‘bioethics’. To call these committees ‘bioethical’, then, is slightly misleading. As bioethics takes on an ever increasing role in policy-making, and as concerns over the nature of this role multiply, we need more considered reflection.

As argued by Tallacchini (*Ibid*), the emergence of ‘ethics’ as an “advisory normativity” (Tallacchini, 2009, p. 290) in the EU context has several characteristics, two of which are particularly relevant for the discussion here. First is the “expertised and technocratic” characteristic of EU ethics. This has resulted in a situation where ethics is treated as another type of ‘scientific’ advisory committee. It is one where ethics

¹⁵⁴ The reader will recall from the methodology chapter (Chapter 4) that ‘ambiguity’ in an MCM analysis is a quantitatively based concept of the amount of disagreement between the most optimistic and pessimistic scores, respectively, for each participant in each group.

itself is made objective and the imposition of technocratic values serves to undermine the very purpose of exploring the more ethically and morally subjective nature of scientific facts, values and technology impacts (ibid., p. 291).

The second characteristic relates to the problem of ‘outsourcing’ values (ibid., p. 295). Here, the problem is still related to the ‘expertisation’ of ethics, but extends beyond this to the problems raised by utilizing ethics as a prescriptive input to policy-making. In this sense, ethics provides another means through which decisions might be ‘closed down’ (Stirling, 2008) through singular, prescriptive appraisal and decision-making processes. In the case here, the situation is made all the more troubling for the fact that ethics is used as a way to argue that citizens are being empowered. According to Tallacchini, ethical deliberations merely become a means through which policy-makers can claim to be considering multiple views. The point is that whether such views are, actually, considered becomes irrelevant if the bodies are not set up in such a way as to meaningfully foster broad-based discussions.

In light of the findings reviewed above and in Section 8.3, this view can be both supported and critically elaborated upon. It is supported in the sense that the findings above seem to suggest that the relative ‘distance’ of bioethics from policy is not so great when it comes to the actual *recommendations* that emerge from bioethicists’ deliberations. However, the fact that there does seem to be a difference in the perspectives on good governance between the two stakeholder groups raises questions about the extent to which there may be an inherent failure in bioethical advice, itself.

Though some bioethicists participating in this study sat on national or international bioethics ‘official’ advisory bodies, not all do. However, all work in some way with the policy ‘world’ – either through their role as bioethics advisors to professional member organisations or as informal advisors to policy-makers. Thus, it is important to recognise that even amongst academically grounded bioethicists, the language and framing of the issues is different, but the governance choices are similar. This seems to support Tallacchini’s arguments that bioethics in a policy-making context does not fulfil its mandate of representing cultural pluralism and diversity, but also suggests that there is not cause for despair. Instead, the flaw may lie in the extrapolation of bioethics into a policy-making context. Therefore, we suggest a more critical and cautious stance is needed regarding the relationship between policy-making and the legitimacy language of bioethics.

The findings from Section 8.3 further support this assertion. We saw there that it is those directly involved in policy-making who are more keen to frame governance in the light of moral and ethical language, rather than socio-political and institutional factors. This raises the question as to why there seems to be an unwillingness among policy-makers to ‘let go’ of the ethical rhetoric? One possible answer lies in the ideas that ground this thesis. The context of hESC research is one where facts are uncertain, conditions unknown, assumptions varied and stakes of all kinds are high. Such circumstances pose challenges to policy-makers as they grapple with how to approach governance and keep apace with the science. As Jasanoff’s earlier quote points out, and as Tallacchini’s work suggests, bioethics has become one way in which the uncertainties and the unknowns seem to become more manageable. Moreover, it is a way to respond to the demands for increased public involvement and accountability, which have been a rallying cry among publics and academics alike for many years.

The arguments discussed at the beginning of this section claim that governments favour ethical inputs to policy-making because they can lay claim to having considered a broad range of societal and cultural values, but without having to show how they have considered them. By invoking the language of ‘ethics’, they are able to claim consideration of subjective concerns, but in an ‘objective’ light which suits their pragmatically inclined policy and decision-making orientation. The findings here suggest that all is not lost with bioethics as an input to policy-making. The perspectives of bioethicists do vary from those of policy-makers, showing that there are new insights being brought to bear on tangible governance issues. The challenge, then, lies in disentangling bioethics from a policy-making context and thinking more critically and cautiously about how to ensure its inputs are truly representative of the cultural and social pluralism underpinning our societies.

8.5 Civic epistemologies

8.5.1 Introduction

Jasanoff’s work on civic epistemologies has been referred to in earlier chapters, but it will briefly be reviewed again here. In her book, *Designs on Nature* (2005), Jasanoff covers an immense expanse of ground looking at the “culturally specific, historically and politically grounded, public knowledge-ways” (ibid., p. 249) in the field of biotechnology. She argues that the implicit public activity of engaging with science

forms an “integral element of political culture in contemporary knowledge societies” (ibid., p. 249). By classifying this activity according to national tendencies, she uses the concept of ‘civic epistemologies’ to critically examine the way publics assess claims, or collectively generate knowledge, about science. Thus, a primary aim of the book is to communicate the idea that the ‘politics of biotechnology’ (ibid.) are deeply intertwined and interdependent on the ‘politics of knowledge’ (Grove-White, 2008). Science and technology are shown to be “central drivers of new ‘knowledge economies’” as they become “ever-more significant agents in the re-shaping of political and institutional relationships” (ibid., p. 182).

Over the course of the book, Jasanoff conducts a comparative analysis of three countries – the US, UK and Germany – with the aim of identifying broad characterisations of each civic epistemology. This is done through detailed case studies in each country’s response to different biotechnology advances. The final chapters consider all of the preceding analysis and culminate in a discussion of how six “constitutive and interrelated dimensions” of civic epistemologies are exhibited in each country (emphasis in below added to reflect dimension names, 2005, p. 259):

- styles of **public knowledge-making** that are constrained by the specific institutional norms and rules of that country;
- methods of ensuring **accountability** (and hence the **basis for public trust**) regarding the information and knowledge provided by experts, policy-makers and other actors;
- practices of **public demonstration** whereby the state acts to demonstrate its scientific capabilities and powers in ways that its citizens will accept and relate to;
- preferred **registers of objectivity** for the state whereby the citizens view the knowledge produced and used in policy-making to be ‘true’ and valid;
- accepted **bases of expertise**, meaning the way credibility is conferred upon experts in the policy realm; and
- **visibility** of expert bodies.

Jasanoff uses these six areas to broadly characterize the US, UK and Germany as having ‘*contentious*’, ‘*communitarian*’ and ‘*consensus-seeking*’ civic epistemologies, respectively. Arising out of the six dimensions described above, these civic epistemologies provide a window into what we would argue (in the language of this thesis) are Jasanoff’s perception of national perspectives on good governance. That is, through her descriptions of how different types of knowledge are co-produced and come to be seen as authoritative in each country, she is identifying nation-specific notions of what constitutes good governance. What is of interest when considering Jasanoff’s

characterisations of perspectives on good governance in comparison with those identified in this thesis, is the way in which each perspective is seen to emerge and through which windows of analysis. Insights of this kind may allow us to empirically contribute both to the concept of civic epistemologies, but more generally to comparative analysis in science and technology studies.

8.5.2 Dimensions of civic epistemologies; dimensions of good governance

Jasanoff begins with a similar premise to that of this thesis: biotechnologies pose unique problems to policy-makers due to their entanglement with a wide array of social, cultural and technological values. However, her analysis ends in a place that focuses on how these policy problems are ‘known’, considered and grappled with by different national publics. This process of appraising, or coming to ‘know’, the technologies and their co-produced relationship with society, is itself a crucial part of understanding how different perspectives on good governance are constituted.

As this research employs a method of technology appraisal, albeit one that has more directly elicited stakeholder views, in comparison with Jasanoff’s elegantly wide-ranging and interpretive contribution, it is conceivable that some of the six identified epistemologies might reveal themselves within the criteria and option evaluations. If this is found to be the case, we might be able to make some comparisons between the two sets of findings and hence contribute to an important area in comparative science and technology studies.

As the three previous chapters have alluded to at times, there are some resonances between Jasanoff’s ideas about civic epistemologies and the nature of the findings from the analysis here in this thesis. These emerge most strongly in two areas – *public trust* and *bases of expertise* – and less strongly, but nonetheless worth commenting upon, in the dimension of *preferred registers of objectivity*. Before comparisons are made, a note of caution must be sounded. First, it is not our intention to claim that our findings are more robustly grounded than Jasanoff’s, which covers many academic disciplines, countries and areas of technology. However, it is also the case the study here employed a unique methodology aimed at both opening up the implicit and explicit processes through which governance options are socially and technologically appraised. Moreover, it does so in a way which allows for distinct socio-political points of view to be probed in a symmetrical way and their implications explored. As has been

shown in the analysis, these implications arise at both national as well as individual stakeholder group levels. Therefore, though the two data-sets are derived in different ways, the aims in understanding the complexities of the relationship between science, technology and society and the themes of socio-political governance are broadly the same. Thus, we might expect the findings to be mutually enlightening.

Beginning with public trust, Jasanoff argues that the bases for trust in different countries arise from the types of public accountability that are offered. She points to the processes of judicial litigation in the US as the primary way in which the credibility of scientific claims are established. “Truth, in this template, emerged only from aggressive testing in a competitive forum” (Jasanoff, 2005, p. 260). Public accountability in the UK, on the other hand, is conferred through the proclamations of official expert bodies. This, Jasanoff argues, is due to a more “insulated” regulatory process, which allows for experts to gain credibility through years of working in public service. This seems to suggest that the basis of trust and expertise are intimately linked in the UK civic epistemology.

The empirical findings in this thesis can be interpreted as supporting and critically elaborating on Jasanoff’s claims. In Chapter 6, we discussed how, for UK stakeholders, trust seemed to be heavily dependent upon institutional processes. Numerous stakeholders suggested that it was the regulatory process itself which would instil public trust. Thus, to the extent that this complements Jasanoff’s findings that public accountability in the UK is related to the insulated regulatory process, we find a consistent pattern. However, the findings of this thesis diverge slightly when we consider Jasanoff’s claim that it is the experts themselves who bestow accountability on the regulatory process, and hence provide the basis for trust in the regulatory system. We argue this may not be exclusively the case. Rather, the participants interviewed for this research felt that public accountability resides in the processes themselves, both in relation to the individuals involved, but also in relation to the nature of the system. In other words, the two are mutually dependent. One could not have corrupt or inexperienced individuals on regulatory bodies as this would lead to a loss of accountability. However, it is also the case that if the institutions and instruments of government were set up to be publicly accountable, the experts on them would not last if they were seen to be lacking in a particular key characteristic. It seems, then, that the UK-based perspective on trust as characterised in this thesis is grounded in a fuller exploration of the *multiple* foundations of trust that might arise from and within a

nation's institutional configurations. It is these multiple foundations that serve to establish accountability and give rise to the ways in which publics come to bestow their trust in government institutions.

It was difficult to identify a single pattern within the US perspective on public trust as analysed in earlier chapters. Despite this, it is clear that litigation as a basis for establishing accountability, as argued by Jasanoff, did not actually feature in stakeholder perspectives on good governance within this thesis. Rather, there was a tension exposed between notionally 'democratic values' which might be expressed either through attention to cultural pluralism or establishment of broad-based deliberation mechanisms. To this end, we do find some resonance with Jasanoff's discussion of public trust in the US as being grounded in 'assumptions of distrust'. That is, government decisions are assumed to be invalid until proven in some way – in her argument through the litigation system.

For the participants interviewed in this thesis, however, assumptions of distrust seemed more derived from a dissatisfaction with the current governance system in the US and the way it was arrived at. For example, doubt was expressed by some US-based stakeholders about the ability of institutions to make the 'right' decisions about good governance. This was apparent in the finding that more 'outcome-based' and instrumentally motivated criteria dominate the US stakeholder group's perspectives on good governance. Additionally, others expressed a desire for 'real public discourse' to inform governance decisions. However, this criterion was elaborated on by discussing how 'closed' the policy-making process for hESC research was within the Bush administration and how it did not reflect the majority views of the public. The fact that my findings are tangential to Jasanoff's claims is not to say they are contradictory. Rather, we can only reiterate that legal challenge as a means of addressing distrust was not mentioned by interviewees and therefore may not be a dominant mode of generating public accountability for this particular area of biotechnology.

Expertise is the second dimension of civic epistemologies which we can explore in relation to the findings of this thesis. Jasanoff argues experts have a heightened importance in the decision-making process for biotechnology, and indeed are "indispensable to the politics of knowledge societies. They [experts] tame the ignorance and uncertainty that are endemic to modernity..." (Jasanoff, 2005, p. 267). Therefore, culturally specific ways of identifying and coming to 'know' expertise can be identified. Jasanoff argues that the identification of experts rests upon the balance between their

formal qualifications and their personal or institutional experiences. In the UK the status of expertise is conferred through one's history of service to the country, whereas in the US expertise comes from one's professional status and standing.

The findings of this thesis do not reveal anything specific about individual traits of experts, so direct comparisons cannot be made on this end. Rather, the perspectives on good expertise identified in this thesis focus on more general characteristics of the relationship between expertise and good governance. Consequently, there may be an important difference in the application of the term 'expertise'. For hESC research, the view among MCM interviewees in both the US and the UK was that expertise needed to be balanced and to represent a wide range of views and types of experts. What differed between the two countries was the emphasis on the role of expertise within a wider context of good governance. UK-based perspectives tended to emphasise the types of experts needed on regulatory bodies, whereas US perspectives tended to emphasise the types of inputs and role experts should play in decision-making. In this, the former was more process-based – good experts lead to good processes of decision-making – whereas the latter was more outcome-based – good inputs lead to the 'right' outcomes for hESC research.

It seems, then, that in the case of hESC research, the important feature on which expertise rests and comes to be seen as reliable is not only the type of knowledge individual experts embody, as Jasanoff argues, but the way this knowledge relates to governance as a socio-political process. Again, the empirical findings of this thesis, display a degree of non-alignment with Jasanoff's arguments. Here, it is perhaps the case that the dimension of expertise as presented by Jasanoff is simply framed in a more narrow way than was conceived of by stakeholders interviewed here. If this is the case, we might see further evidence of this within the final civic epistemology dimension of 'objectivity'.

The dimension of objectivity is defined by Jasanoff as relating to how publics determine whether knowledge is reliable. "Objective knowledge is by definition reliable public knowledge, for such knowledge looks the same from every standpoint in society; it is untainted by bias and independent of the claimant's subjective preferences" (Jasanoff, 2005, p. 264). In the US, Jasanoff argues that objective knowledge rests on the "language of numbers" (ibid., p. 265). Decisions are made based upon the results of quantitative risk assessments, and (despite outcries of the type reviewed in Chapter 3) risk assessment and 'sound science' rhetorics came to be linked in the US

biotechnology regulatory discourse. In the UK, risk analysis is also a feature of objective knowledge, but so too are the experts who are conducting the analyses.

In [the UK], appropriate political representation remains part and parcel of the process of risk analysis, consciously built into the design of expert committees and consultative processes... (Jasanoff, 2005, p. 266).

Both points seem to hold true for the empirical findings presented in this thesis, but to varying extents. This is most notable in the case of the US-based perspectives identified here, where the endorsement of Jasanoff's claims are somewhat mixed. Some interviewees expressed a desire to have wider public inputs to 'objective' processes of decision-making, seemingly a move away from 'expert-based', technocratic and quantitative processes of generating objective knowledge, while others appeared staunchly opposed to having anyone except experts sitting on advisory committees and making regulatory and policy oversight decisions. One could hypothesise that in the case of those asking for more broad-based public deliberations, this was a result of the desire to see actual public inputs to decision-making processes, as opposed to the "instrumentally selected experts" of the Bush administration (Jasanoff, 2005, p. 266). Equally, such 'instrumentally selected experts' can be seen as favourable or unfavourable depending on one's ideological viewpoint. The problem with assertions of either type is that 'ideological bias', or 'objectivity', is in the eye of the beholder. Thus, though there were calls for 'evidence-based' decision-making, such perceptions of objectivity can vary within countries or between stakeholder groups. Jasanoff's claims, then, while perhaps true in broad terms, may be on shakier ground when considered in this way.

To conclude, the findings of this thesis both support, but also critically elaborate on, Jasanoff's concept of civic epistemologies. It is in this spirit that we offer a final point. The findings of this thesis support the assertion that perspectives on good governance are not only discernible at different levels, but they also display systematic patterns when compared between national, intra-national and individual stakeholder levels. Thus, perhaps more relevant than the national points of comparison in relation to Jasanoff's concept of civic epistemologies, are the implications of the findings that *multiple* perspectives on good governance reveal different and contrasting socio-political points of view with implications for assessments of how, and for what reasons, different governance options are viewed as favourable. This lends support to the broader hypothesis of this thesis that comparative analysis at one level is rarely sufficient for full

understanding of the complexities of divergent social, political and cultural understandings of good governance.

8.6 Conclusion

This chapter has drawn together the various empirical, theoretical and methodological strands of this thesis. We identify contributions to the academic literature in four different areas. First, we contribute empirically to, and critically elaborate on, an emerging area of theoretically grounded literature relating to the different rationales underlying technology appraisal strategies. Normative, instrumental and substantive imperatives were found to offer a meaningful way to partition and understand key drivers of contrasting perspectives on good governance across multiple stakeholder groups. An empirical contribution to recent thinking in technology governance literatures is made.

Second, the moral and ethical issues relating to good governance are explored. We highlight and offer explanations for the greater use of *moral and ethical* language by policy-makers and regulators and within the policy documents themselves to discuss governance as compared with the greater focus on *socio-political and institutional* factors by the majority of stakeholders interviewed. This leads to the third contribution, that of the increasing role of bioethics in the governance of biomedical technologies, especially human embryonic stem cell research. Bioethicists and policy-makers and regulators are shown to have divergent, qualitatively-deduced, perspectives on good governance, but convergent, quantitatively-identified, assessments of option performance. These findings are used to support the idea that in order for bioethics to contribute meaningfully to policy and governance in this area, it might cautiously and critically evaluate its relationship with, and use of, legitimacy languages of bioethics. Finally, Jasanoff's seminal concept of civic epistemologies is reviewed and comparisons between her theoretical contributions and the empirical findings of this thesis are explored.

The final chapter will summarise the four overarching contributions of this thesis, covering the theoretical, empirical, methodological and policy-relevant conclusions that can be drawn. Suggestions for additional research are offered.

9. Conclusions, future research and policy implications

9.1 Overview

Biomedical technologies like hESCs push the boundaries of how we define ourselves as human. Accordingly, they can involve complex and entangled interactions between public values, cultural norms, institutional interests, societal expectations and technological uncertainties. These entanglements pose serious governance challenges. This thesis has therefore addressed ‘good governance’ of hESC research as both an analytical subject and as an imperative for rigorously testing novel forms of technological appraisal which might address such challenges. Using one such method (MCM), we have explored contrasting perspectives on what constitutes good governance for hESC research and asked whether – and what kinds of – systematic patterns are discernible between perspectives of UK and US policy actors. These perspectives have been empirically investigated through a research framework that combines dimensions of qualitative sensitivity and quantitative precision, as well as symmetry, transparency and reflexivity, in documenting the nuances of different perspectives. In this final chapter, we will review the main contributions of this thesis, make suggestions for future research and offer tentative recommendations for policy-making in the area of hESC research.

9.2 *Summary of findings and theoretical contributions*

In this thesis, we have provided a reflexive explanation of the main drivers behind contrasting perspectives of policy actors and have made several interlinked theoretical, methodological, empirical and normative contributions to our understanding of good governance in the area of hESC research. The contributions in each of these areas are summarised below.

Theoretically, we have examined the wider governance literature and arrived at a conception of governance appropriate for the context of this thesis. A social-political stance on governance, as introduced in Chapter 3, provided a basis on which we could consider the multiple and co-constituting processes involved in governance, the spheres in which these processes take place, and the implications of the interactions between

them. From there, we moved from the theoretical basis of governance to consideration of the normative interpretations of *good* governance emerging from the wider literature. This allowed us to develop three inter-related dimensions of good governance which were then used as the basis for the methodological development of the MCM options. These dimensions are: 1) the structure of institutional oversight and whether it is **centralised** or **decentralised**); 2) the processes of negotiation, engagement, and deliberation between society and the state in terms of whether they are primarily **technocratic** or **democratic**, and 3) the types of mechanisms and instruments used to govern either as **targeted regulations** or **passive ‘steering’**. Further theoretical contributions that arise from the empirical findings are discussed below.

Methodologically, imperatives for good governance have been established as theoretical groundings for testing a novel form of appraisal. In using – and further developing – the elicitation and analysis method of Multicriteria Mapping, we have systematically and symmetrically explored different perspectives on good governance. As a method, MCM allows us to harness the strengths of both qualitative and quantitative approaches in documenting the divergent socio-political views and sensitivities of framing in the appraisal of governance options for contested technologies. We found that MCM offered a robust social appraisal method capable of engaging a diverse set of participants from contrasting national and stakeholder backgrounds.

We have also made contributions to the development of the methodology in key areas. First, we demonstrated how it can be used to triangulate empirical and theoretical findings within a wider research framework. The theoretical review identified three dimensions of good governance, which were employed within the methodology and found relevant across multiple contexts. The empirical, content-based analysis of the policy literature identified four themes of good governance which were found, independently of direct examination, to be equally salient across the MCM-generated assessments of good governance. Quantitative heuristics were then used to identify areas of analytical interest, which were explored in great depth in the qualitative material underpinning the option assessments and criteria definition. Iterative examinations of the data, such as consideration of additional quantitative measures (mean weightings or expressions of uncertainty and ambiguity) and qualitative insights (explanations of weightings or reasons for uncertainty), were used to confirm or further explore earlier hypotheses. Thus, the three areas of analysis relating to ‘good’

governance were all independently and reflexively conducted, but proved to be mutually supporting in their findings.

Second, in previous uses of the MCM methodology, the process of quantitative and qualitative analysis and aggregation of material for presentation tended to be carried out by separate parties. The work reported in this thesis involved an unusually large number of interviews performed and analysed by a single researcher. Indeed, this is the first time that such a detailed quantitative and qualitative MCM analysis has been conducted on such a scale (whether for the purposes of a doctoral thesis or otherwise).

Empirically, we found systematically contrasting patterns in perspectives on good governance amongst UK and US policy actors, with equally significant points of convergence and divergence. The analysis was structured around four themes of good governance that were identified through a review of national policy documents. In brief, these themes concerned the extent to which good governance: *i*) advances scientific and technological outcomes and addresses related issues in hESC research; *ii*) encourages moral and ethical awareness of hESC research; *iii*) establishes appropriate institutions and instruments of the oversight for hESC research and *iv*) is identifiably grounded in social and cultural bases. These themes were also found to be salient with regard to the MCM findings.

Thus, within each of the themes, divergent perspectives were found within the national policy documents, as well as across and within the different national settings and various groupings of stakeholders. While there was often convergence in the MCM ranking patterns across the governance options, these commonalities tended to obscure the complexities and nuances in framings within the perspectives on good governance. The most prominent of these patterns and distinctions were as follows:

- Contrasting framings of the nature of hESC research in relation to desired **technological and scientific outcomes** were found: *(i)* between the national policy documents of the UK and US; *(ii)* across broad features of stakeholder perspectives in the UK and US; *(iii)* between stakeholder perspectives within the UK and US and, *(iv)* between some aspects of national policy documents in a particular country and corresponding patterns among national stakeholders.
- Though there were divergent framings of the embryo within national policy documents, a general pattern emerged involving greater use of **moral and ethical language** to discuss governance among UK policy documents, policy-makers or policy advisors. In contrast, less attention was given to the moral status of the embryo by the majority of stakeholder interviewees. Instead, there

was a greater focus on how **institutional and socio-political factors** would encourage ethical behaviour and awareness in the context of good governance.

- Further systematic contrasts in characterisations of good governance emerged in the more **process-based** understandings of UK perspectives and the more **outcome-based** views of US perspectives. This was evident in both the national policy documents and in the MCM interviews. This seems to parallel claims made in some theoretical literatures, notably Vogel's study of national styles of regulation in the UK and the US (1986). Taken as a whole, then, the finding suggests a potentially significant general contrast in characterisations of good governance between the UK and US.
- Reliance on **bioethics as a legitimacy policy advisory tool** is evident in both sets of national policy literatures and similarities were found between the ranking patterns of bioethicists and policy-makers within the MCM findings. However, divergent socio-political viewpoints are evident in perspectives of UK and US stakeholders, especially in terms of the ways scientific outcomes are discussed and bases of trust and legitimacy in good governance are established. We therefore suggest a critical evaluation of the relationship between policy advice and bioethics is needed.
- A number of **key drivers behind contrasting framings** of good governance adopted under different perspectives were discerned according to underlying **normative, instrumental or substantive imperatives**. These theoretically grounded imperatives provided a meaningful way of partitioning the empirically-defined criteria and analysing differing option performance patterns. Additional comments about the intertwined theoretical and empirical contribution made on the basis of this finding are discussed below.
- **Consistent patterns in option performance** were found among two of the governance options across a remarkably wide array of perspectives. The detailed centralised oversight option was one of the highest ranking options across all perspectives and under different criteria groupings (or 'issues'). The mixed central/devolved option often displayed the largest difference between highest and lowest rank. This was due to a particularly high degree of uncertainty and ambiguity in this option's performance, indicating greater diversity in associated conditions and assumptions affecting option assessment. These two findings have normative implications for policy-making (discussed below).

From these empirical findings, four further contributions of a more theoretical nature emerge. First, the notion that normative, instrumental or substantive imperatives may lie behind the design of different types of technology appraisal is based in a developing body of literature. Empirical support for such theoretical ideas had

previously been somewhat lacking and the analysis presented in Chapter 8 makes a significant contribution in this respect. Second, in contrast to the moral and ethical framing of governance problems observed in the policy documents, we find that the framings of perspectives elicited from stakeholders are noticeably more socio-political and institutional in character. This suggests stakeholders have moved on from the moral debate over the status of the embryo to wider concerns about the socio-political implications and institutional impacts on the future of hESC science. Third, these differences in the use of moral and ethical language, as well as the findings of convergent ranking patterns among the perspectives of bioethicists and policymakers, raises questions about the reliance on bioethics as a new type of legitimacy expertise. This finding adds to a growing discussion in the theoretical literature about the limitations of bioethics as an objective arbiter of social and moral views. Finally, the identification of systematic patterns in perspectives on good governance across and within national and stakeholder groupings supports the conclusion that while national comparisons are useful for identifying broad tendencies, they risk overlooking important intra-national differences. This suggests, particularly for the area of hESC science, that a greater appreciation of the differences in constitutions of good governance at multiple stakeholder levels is needed in comparative studies of science and technology policy.

9.3 *Suggestions for future research*

This thesis has critically explored the analytical subject of good governance in relation to a specific biomedical technology, hESC research, in two countries, the US and the UK. Moreover, it has addressed good governance as an imperative for testing a novel form of technology policy appraisal. Suggestions for future research, then, might be considered in relation to the subject of the research as well as its methodology.

In order to further our understanding of the normative concept of ‘good governance’, it would be useful to examine another area of biomedical technology, or even an area of environmental or industrial technology that raises similar conditions of risk and uncertainty. It would be useful to see whether – and what kinds of – convergent and divergent patterns in perspectives on good governance lie across and within different technologies. This would enable us further to understand the normative

implications of good governance for policy-making, as well as enable theory-building in comparative literatures on science and technology governance.

Methodologically, MCM itself has been tested and developed in new ways in the course of this research. However, the methodology does have certain limitations and further research could be undertaken to test its robustness. To this end, the same research could be repeated, but with a different appraisal methodology such as Q-method (discussed in Chapter 4). Though the purpose of Q method and the resulting findings are different from those obtained in an MCM study, the principles of social appraisal in an open, participant-led format, are similar. Thus, such findings could be used in comparison to the findings here and development of both methodologies might result. In addition, further development could be taken to explore the use of statistics within an MCM study, as alluded to in Chapter 4.

9.4 *Policy implications*

We are now in a position to address the normative implications of policy-making for how good governance of biomedical technologies, specifically hESCs but other technologies as well, might be conducted under conditions of risk, uncertainty and ambiguity. A note of caution should first be sounded, however, before such implications are discussed. The central component of this research has been to explore contrasting perspectives on good governance in different national and stakeholder contexts. This has required a detailed appreciation of the social, cultural, political and institutional factors that influence the framings adopted in different perspectives. The following policy-relevant conclusions are offered while at the same time recognising the nuances, complexities and sensitivities inherent within national and cultural policy-making contexts, as well as between them, that this thesis has sought to explore. However, despite the different ‘voices’ and ‘perspectives’, common features of good governance emerge despite, or perhaps in spite of, the divergences in how these notions of good governance come to be constituted and the assumptions, judgements and views that frame and condition them.

The consistently high performance ranking of the detailed centralised oversight and more uncertain and ambiguous assessment of the mixed central/devolved option suggest there are key features of hESC governance that are favoured across multiple contexts and perspectives. Specifically, some type of centralised institutional oversight

appears more desirable than other options. Centralised oversight can provide consistency and stability for the science, as well as fostering trust among the public in ways that were broadly welcomed by a diversity of stakeholders in both the UK and the US.

This is interesting in relation to the US context because there have been many state-based initiatives for governing hESC research emerge in recent years. The findings here suggest that the presence of such multiple and varied governance frameworks within one country may do more harm than good to the progress of hESC research because it makes scientific collaboration harder and hinders scientific advance. On this basis, we recommend a re-evaluation of this trend in the US and that greater efforts are made to standardise funding, regulatory and commercialisation policies across the country. This is not to suggest a fundamental re-evaluation of the federal system, but rather a greater appreciation of the burdens current governance regimes pose to scientific advance.

In relation to the UK context, the findings suggest that frequently invoked complaints about ‘regulatory burdens’ are, perhaps, exaggerated by some stakeholders. Centralisation and strong regulations help to stabilise the platform on which science can develop and technological advances are made. Moreover, the perception that science is being actively monitored seems to help allay fears of ‘franken-babies’ and thus fosters public trust. This, in turn may help to advance the field by reducing public opposition. Future policy-making in the UK should celebrate the strong framework it has established over the years in this field, but should also ensure the same attention is paid to supporting technological developments from fundamental advances in hESC research.

Though these conclusions are made on the basis of research into hESC governance, the basic principles seem to ring true for other areas of biomedical research, or indeed other technological areas that carry with them a high degree of social and cultural, as well as scientific, uncertainty. Here, as with hESC research, there may also be an argument for centralised oversight of scientific advance which can also be understood from the two related objectives of scientific advance and public safety. But, perhaps more fundamentally, we find it striking that there was a preference among all participants *for some role of government* in the pursuit of ever-more complex technologies which pose social and scientific risks, introduce uncertainties and highlight ambiguities. We could have found a view that placed scientific advance as an

unquestionably ‘good’ objective in itself and to that end should be left alone by the state. Instead, however, we find a much more nuanced discussion prevails in relation to the mutually dependent and intertwined roles of the state, the public and science in a governance system.

These nuances are apparent in the findings related to the role of engagement and deliberation around technological futures. Attempts to engage the public through national dialogue and deliberation about the future of risky and uncertain technologies should be made in a manner that is most appropriate for the different cultural and historical contexts. For hESC research there were variations in the extent to which this was seen as being most appropriately mediated through mechanisms of public engagement, or through expert bodies. In either case, there was an interesting preference among stakeholders in both countries for devolved governance when assessing criteria about the role of the public. This seems to suggest a more general point about the importance of ‘locality’ in governance structures. Though this may seem to contradict the earlier finding about centralised oversight, it actually seems to suggest there are tangible lessons for the nature and conduct of public engagement. The more local the governance system, the more potential there might be for public input to be heard, and considered.

This leads us to a further reflection on the implications for governance of biomedical technologies that challenge social and cultural norms. It is our view that there are lessons for policy-makers in the need to critically evaluate how and why bioethics is used as a policy advisory tool when it comes to the future of biomedical technologies. There are benefits to employing principles of ethical and moral thought in a technological area rife with conflict on such issues. However, the tendency in policy-making seems to have been for bioethics to be used more to legitimate difficult policy choices and less as a critical tool for engaging with cultural and social pluralism. What is presented as a subjective exploration of social views has instead become an exercise in translating ‘ethical’ advice into another form of ostensibly objective technical expertise. Policy-makers are not wrong in identifying the *potential* of bioethics to enrich governance discussions and interactions in the area of biomedical technologies, but the mechanisms through which this occurs should be examined. To employ the language of imperatives used earlier, the danger lies in an instrumental use of bioethical advice for the achievement of specific policy ends.

To this end, this thesis has shown there is clear potential in the use of social appraisal tools like MCM to understand and appreciate the diversity of views and sensitivities inherent to different publics, including different ‘experts’ and policy actors, in the consideration of technology policy options. In ‘opening up’ the reasons for and rationales behind different option assessments and appraisal strategies, we are more easily able to identify areas of synergy between seemingly divergent points of view and stakeholder perspectives, as well as technology choices themselves. To the extent that a finding of this thesis relates to the importance of fostering meaningful understanding of the implications of divergent views on technology choice within a society, methods of appraisal such as MCM provide practical options for widespread policy use at both national and local levels.

At some point in the past, it might have been argued that scientific progress took place relatively unimpeded by political, cultural and ethical issues. Today, however, a host of issues are recognised as both constraints and drivers of scientific advance. This is especially so with technologies like human embryonic stem cell research, which literally deconstruct and reassemble the building blocks of human life for scientific study and medical advance. There is great promise in this biomedical technology, but also great uncertainty, as it remains unproven in a therapeutic setting and poses risks that extend beyond the medical realm and into the social and cultural. By exploring how governance itself is presented in wider academic and political contexts, we have offered a critical, reflexive and explanatory view on how different stakeholder perspectives believe *good* governance of human embryonic stem cell research should be constituted. We hope to contribute to ongoing debates about how, and in what ways, technological advance and cultural sensitivity might mutually reinforce and inform each other in a modern world.

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Annex A – Individual US state policy summaries for hESC technologies

Table A.1: Summary of State-based initiatives in support of hESC technology¹⁵⁵

State	Summary of support initiative
California	In November 2004, California voters passed Proposition 71 which requires California to raise over \$3 billion in state bond money that would be dedicated to stem cell research. In addition, it amended the state constitution to explicitly prohibit human reproductive cloning, but allow for human embryonic stem cell research, including nuclear transfer. The California Institute of Regenerative Medicine (CIRM) was established to administer the research funds and is overseen by an Independent Citizens Advisory Committee, which has a detailed set of institutional rules governing its actions and activities.
Connecticut	In 2005 a fund was created to support ESC research which would allocate £10 million/year over 10 years. An oversight panel reviews research applications and makes grant decisions. The first grants were awarded in 2006.
Illinois	In 2006, an Executive order signed by the Governor authorised £10million in funding and set up the Illinois Regenerative Medicine Institute (IRMI). The first grants were awarded in 2006. In 2007 state legislature passed bill permitting IRMI to conduct stem cell research on cells from any source.
Indiana	The state says that it actively supports adult stem cell research, but this is only at one research centre at Indiana University and there is very little funding (~\$50,000 by 2008 estimates). Legislation passed in 2005 that prohibits reproductive and therapeutic cloning.
Massachusetts	In March 2005, the Massachusetts legislature overwhelmingly passed a bill clarifying state law on hESC research and therapeutic cloning, ensuring both types of research are permitted within a regulatory framework. Though the (then) Governor (Mitt Romney) vetoed the legislation, this veto was overruled by a further vote in the House and Senate. Despite this, as of 2006, no state funding had been allocated for hESC research.
Maryland	The Maryland Stem Cell Research Fund was established in 2006 and provides grants for both adult and embryonic stem cell research. By the end of FY2009, the fund had committed to \$56 million across 140 different research projects. The projected funding for FY 2010 was \$12.4 million.
Missouri	In Missouri, voters have approved a constitutional amendment protecting hESC research, but there is little political will in the state legislative bodies and nothing has happened in the way of funding the research.
New Jersey	New Jersey was the first state to appropriate funds specifically for adult and ESCR. However, a ballot initiative in 2007 which would have created a state stem cell fund and provided capital funding for a new research centre was voted down. This was attributed to low voter turnout and a state budgetary crisis. Not long after the vote, construction on the promised stem cell facility was quietly closed down.
New York	In 2007, state legislators created The Empire State Stem Cell Trust. This sets aside \$100million for fiscal year 2007-08 and \$500million, to be allocated at \$50million per year for 10 years beginning in fiscal year 2008-09. The approval of research projects and administration of the funds are overseen by the Empire State Stem Cell Board. There are several committees which sit within this board and have responsibility for approval of research, allocation of funds, and ethical oversight.

¹⁵⁵ This table is based on information provided by the National Conference of State Legislatures, available at NCSL, <http://www.ncsl.org/default.aspx?tabid=14413>, Accessed 12 April 2010.

State	Summary of support initiative
Ohio	The Center for Stem Cell and Regenerative Medicine was opened in 2003 with an initial funding of ~\$20m. Only human adult stem cells are studied at the center and the governor previously has vetoed language prohibiting hESC research (2005), but no state funding for lines outside of President's policy.
Washington	In 2008 the state created a Life Sciences Discovery Fund, however little headway has been made since.
Wisconsin	Despite being one of the 'birthplaces' of hESC research, there is a relatively negative political climate in the state legislature, but a very supportive Governor. The state previously has provided \$750 million in public-private investment for biotech, health sciences and SCR. The state legislature has tried to prohibit reproductive and therapeutic cloning, but the governor repeatedly has vetoed the legislation.

Table A.2: State-by-state summary of legislation on foetal tissue and embryo research¹⁵⁶

State	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo ³	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Arizona	No	Yes, prohibits research on aborted living/non-living embryo or fetus	No	Yes, prohibits the use of public monies for cloning for research	No
Arkansas	No	Yes, prohibits research on aborted live fetus	Yes, consent to conduct research on aborted fetus born dead	Yes, prohibits research on cloned embryos	Yes, prohibits sale of fetus/fetal tissue
California	Yes, permits research on adult and embryonic stem cells from any source	Yes, prohibits research on aborted live fetus	Yes, consent to donate IVF embryo to research	Prohibits sale of embryos and oocytes; prohibits payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research	Yes, prohibits sale for the purpose of reproductive cloning or for stem cell research
Connecticut	Yes, on embryos before gastrulation (a process during embryonic development)	No	Yes, consent to donate IVF embryo to research	No	Yes, prohibits payment for embryos, embryonic stem cells unfertilized eggs or sperm donated following IVF treatment

¹⁵⁶ This table is based upon one provided by the National Conference of State Legislatures, available at NCSL, <http://www.ncsl.org/default.aspx?tabid=14413>, Accessed 12 April 2010.

State	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo ³	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Florida	No	Yes, prohibits on aborted live fetus	No	No	No
Illinois	Yes, permits research on embryonic stem cells, embryonic germ cells and adult stem cells from any source	Yes, prohibits on aborted living/nonliving fetus	Yes, written consent to perform research on cells or tissues from a dead fetus other than from an abortion	Yes, prohibits research on fetus/fertilized embryo; prohibits funding under E.O. 6 (2005) of research on fetuses from induced abortions and the creation of embryos through the combination of gametes solely for the purpose of research	Yes, prohibits sale of fetus/fetal tissue; prohibits purchase or sale of embryonic or fetal cadaveric tissue for research but permits reimbursement for removal, storage and transportation for research
Indiana	Yes, permits fetal stem cell research on placenta, cord blood, amniotic fluid or fetal tissue	Yes, prohibits research on aborted living/non-living embryo or fetus	Yes, consent required for fetal stem cell research	Yes, prohibits research on cloned embryos	Yes, prohibits sale of human ovum, zygote, embryo or fetus
Iowa	Yes, ensures that Iowa patients have access to stem cell therapies and cures and Iowa researchers may conduct stem cell research	No	No	No	Yes, prohibits transfer or receipt of the product of human reproductive cloning
Kentucky	No	No	No	No	Yes, prohibits sale of fetus/fetal tissue
Louisiana	No	No	No	Yes, prohibits research on fetus/embryo in utero, in vitro fertilized embryo	No
Maine	No	No	No	Yes, prohibits research on fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits sale of fetus/fetal tissue

State	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo ³	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Maryland	Yes, permits research on adult and embryonic stem cells	No	Yes, written consent to donate unused IVF material to research	Yes, prohibits donation of unused oocytes for state funded stem cell research; cloning of an organism beyond the embryonic stage is prohibited	Yes, prohibits valuable consideration for the donation or production of IVF material
Massachusetts	Yes, on embryos that have not experienced more than 14 days of development (not including days frozen)	Yes, prohibits research on embryo/live fetus	Yes, written consent to perform research on a dead fetus and informed consent to donate egg, sperm, or unused preimplantation embryos created for IVF	Yes, prohibits research on live embryo or fetus; also prohibits creation of fertilized embryo solely for research	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes; prohibits sale of embryos, gametes or cadaveric tissue for research
Michigan	No	Yes, live embryo/fetus	Yes, written consent of mother to donate dead embryo, fetus or neonate to research	Yes, prohibits research on a live embryo or fetus, cloned embryo	No
Minnesota	No	No	No	Yes, prohibits research on a live embryo or fetus up to 265 days post fertilization	Yes, permits the sale/purchase of cell culture lines from nonliving human conceptus
Missouri	No	Yes, prohibits research on a fetus alive pre-abortion	No	No	Yes, prohibits receipt of valuable consideration for aborted fetal organs or tissue
Montana	No	Yes, prohibits research on a live fetus	No	No	No
Nebraska	No	Yes, prohibits research on aborted live fetus or the use of state funds for research on fetal tissue obtained from an abortion	No	Yes, limits the use of state funds for embryonic stem cell research; restrictions only apply to state healthcare cash funds provided by tobacco settlement dollars	Yes, prohibits sale, distribution or donation of viable aborted child
New Hampshire	No	No	No	Yes, prohibits the maintenance of a unfrozen fertilized pre-embryo past 14 days	Yes

State	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo ³	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
New Jersey	Yes	No	Yes	No	No
New Mexico	No	No	No	Yes, prohibits research on a fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits abortion for the purpose of selling the fetus to researchers
New York	Yes, permits research on adult and embryonic stem cells from any source	No	No		
North Dakota	No	Yes, prohibits research on a living/non-living embryo or fetus	Yes, requires consent to conduct research on a nonliving fetus or embryo other than from an abortion	Yes, prohibits research on a fetus born or extracted alive; cloned embryos	Yes, prohibits the sale of a fetus to be used for illegal purposes
Ohio	No	Yes, prohibits research on a living/non-living embryo or fetus	No	No	Yes, prohibits sale of fetus or fetal remains from an abortion
Oklahoma	No	Yes, prohibits research on a fetus/embryo	No	No	Yes, prohibits sale of fetus or fetal remains
Pennsylvania	No	Yes, prohibits research on a live embryo or fetus	Consideration may not be given to mothers consenting to research; in cases involving abortion, consent must be provided after decision to abort	No	Yes, consideration may not be given to mothers consenting to research or other transferring tissue except for expenses involved in actual retrieval, storage, etc.
Rhode Island	No	No	Yes	Yes, prohibits research on a fetus/embryo born or extracted alive, only applies to in vitro fertilized embryos post-implantation	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes
South Dakota	No	Yes, prohibits research on a living/non-living embryo or fetus	No	Yes, prohibits research on embryo outside of a woman's body; research on cells or tissues derived from an embryo outside a woman's body	Yes, prohibits sale of embryo

State	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/embryo	Consent provisions to conduct research on fetus/embryo ³	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Tennessee	No	No	Yes, consent required to conduct research on aborted fetus	No	Yes, prohibits sale of aborted fetus
Texas	No	No	No	No	Prohibits sale of fetus/fetal tissue
Utah	No	No	No	Yes, prohibits research on a live fetus, fertilized embryo post-implantation ¹	Yes, prohibits sale of fetus/fetal tissue; also prohibits sale of live unborn children, which is not defined, but are referred to in abortion statute ¹
Virginia	No	No	No	May prohibit research on a cloned embryo or fetus ²	Yes, prohibits shipping or receiving of the product of human cloning for commerce ²
Wyoming	No	No	No	No	Yes, prohibits sale, distribution or donation of live or viable aborted child, defined to include embryos, for experimentation

1. Abortion is defined as a procedure undertaken to terminate a human pregnancy after implantation of a fertilized ovum or kill a live unborn child. Therefore, the statute may cover only *fertilized* ovum.
2. Virginia law does not expressly prohibit research on cloned embryos, but it is forbidden to possess the product of human cloning. Under the state human cloning statute human cloning is defined as the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed. Human being is not defined as to whether it includes neonates, embryos or fetuses only.
3. Some states have requirements for consent regarding the disposition of human embryos prior to in vitro fertilization that may impact donation to research.

Annex B – Development of Multicriteria Mapping options

The Multicriteria Mapping (MCM) options for this thesis are structured according to the ‘dimensions of governance’ which were presented at the end of Chapter 3. These dimensions include: 1) is the principal governance mode centralised or devolved? 2) do mechanisms for regulatory oversight provide detailed prescriptions or general guidance? And 3) are associated deliberative processes ‘democratic’ (participatory) or ‘technocratic’ (expert-based)? Beginning with these dimensions, the option definition process proceeded in an iterative fashion through two independently conducted stages. The first of these stages was to develop eight ‘abstract’ options based on the potential combinations of the three central dimensions.

First, building upon these three dimensions of governance, eight ‘abstract’ options were developed based on the possible combinations of the three central dimensions. An example of the working titles of these abstract options are as follows and their full descriptions can be found in table B.1 below:

1. *Centralised, democratic, guidelines*
2. *Centralised, democratic, prescriptions*
3. *Centralised, technocratic, guidelines*
4. *Centralised, technocratic, prescriptions*
5. *Decentralised, democratic, guidelines*
6. *Decentralised, democratic, prescriptions*
7. *Decentralised, technocratic, guidelines*
8. *Decentralised, technocratic, prescriptions*

To give an idea of how the options were then defined, let us look at one of the discretionary options that was ultimately used in the MCM interviews. The following is the definition of the option ‘Devolved democratic governance’ and is analogous to working title #6 above:

Devolved democratic governance through general laws: Oversight of hESC research is devolved from the national level to individual jurisdictions. A high degree of autonomy is given to researchers within a broad set of general laws. Laws are set and interpreted by individual jurisdictions. Both the setting of laws and their interpretation are subject to serious provision for deliberations and negotiations that include significant public involvement initiatives involving a wide range of experts, stakeholders and citizens.

As one might observe in reading through the option, the definition is rather abstract. Defining a set of core options in this way would both seem to be unwieldy and potentially confusing for the interviewee, especially when compounded by an interview process which most participants are unfamiliar with. In order to mitigate this, the governance options were built around country-specific examples. Thus, the second stage of the option definition process was to review national governance frameworks.

Major countries active in hESC research were identified and their national policies reviewed. A particularly useful starting point was the policy report on human assisted reproductive technologies delivered by Fukuyama and Furger (2007) which extensively reviewed international policies for this area. From this basis, further reviews within a relatively distinct body of national policy, theoretical and grey literatures discussing regulatory policies for stem cell research were conducted. This review confirmed that, as is the case in the Fukuyama and Furger report (2007), there are a core group of countries that are discussed most frequently and consistently within these literatures. On this basis, the following ten countries were selected for detailed review and consideration as candidates on which to base the MCM options: the United States, the United Kingdom, Sweden, Germany, Canada, Australia, Italy, Israel, Singapore, and Switzerland. A summary of this review can be found in Table B.2 below.

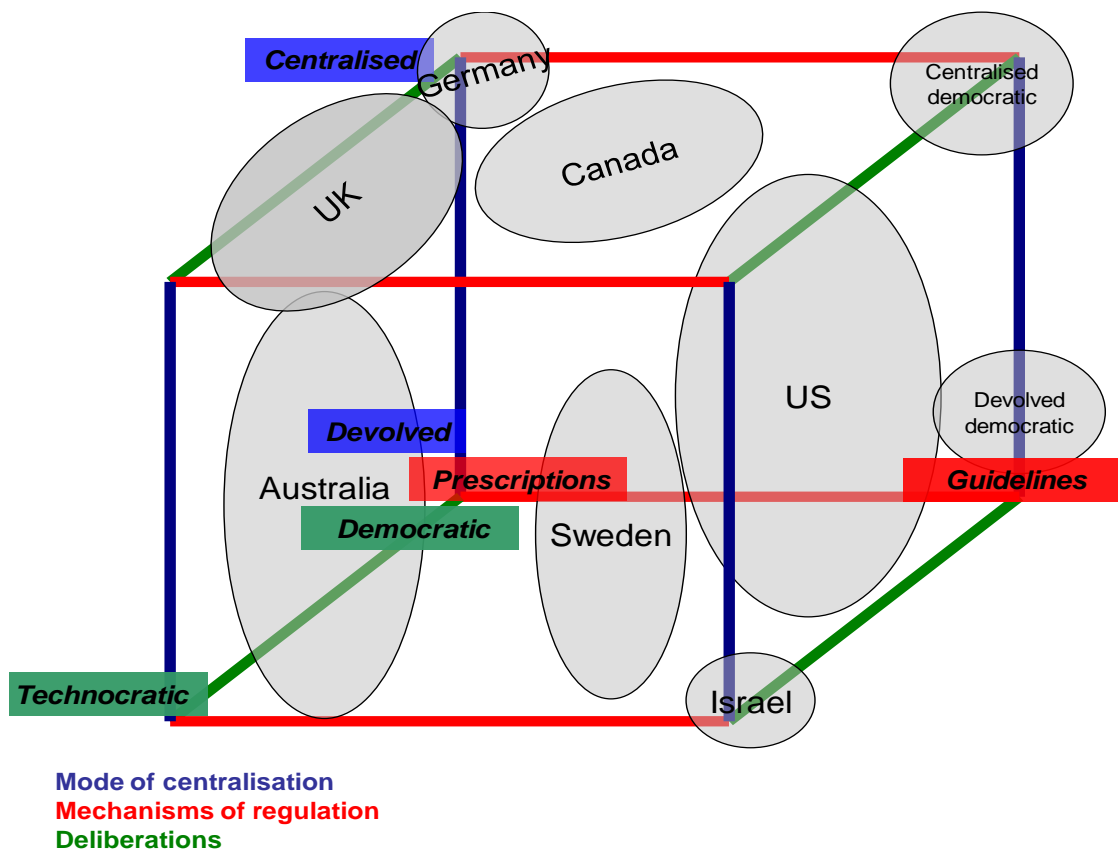
With the ten countries and the eight abstract options identified, a ‘matching’ process commenced. The aim was to identify a core set of options which were grounded in the abstract dimensions, but were based on country-specific models. This was an iterative process which simultaneously required ‘operationalising’ the abstract dimensions of governance whilst ‘generalising’ each country’s individual governance framework. In order to ensure this was done in a systematic manner, several criteria were used as a guide:

- *the final set of selected countries needs to cover, to a reasonable extent, all eight abstract notions of governance as set out above;*
- *it should be reasonable to assume that participants would be knowledgeable about the countries selected;*
- *the governance features of the selected countries should be sufficiently different so that they can be distinctly evaluated;*
- *yet the underlying nature of the selected countries should be sufficiently similar so as to control for unwanted bias in participant evaluation;*
- *the governance frameworks of individual countries should be generalisable in a clear and recognisable manner; and*

- *as the US and the UK are the central comparative points of my study, both these countries should be included as final core options;*

Based upon these criteria, the abstract options and the country-specific ones came into alignment. For example, South Korea was eliminated as a potential country because they are a non-Western democracy, while Australia was included because it is a federal state with a highly centralised national system of oversight for hESC research, thereby rendering it both similar and sufficiently different to the US for comparison. Eventually, six core options and three discretionary options were arrived at, covering seven countries. The diagram below depicts all nine options and attempts to illustrate the way they fill the three-dimensional 'space' created by the dimensions of governance.

Figure B.1: Schematic representation of option definition process



After this process was completed, a full set of MCM options could be developed. These are presented in Annex C.

Table B.1: Abstract Governance Options

Option Title	Option Description
Centralised, democratic, passive	Oversight of hESC research is centralised within a single regulatory institution and at a central level of government. Policy making power is vested within that institution, or rests in another centralised authority. The mechanisms for overseeing hESC research are passive and scientists and researchers enjoy a large degree of autonomy to conduct research; although they may be restricted by some overarching norms or formal restrictions. Negotiations about hESC research governance occur between a variety of actors, stakeholders and citizens and the governance process is open to engagement and participation through many channels. Deliberations that occur within the governance structure are informed by a similar variety of views and perspectives and may be expert-based or lay.
Centralised, democratic, regulations	Oversight of hESC research is centralised within a single regulatory institution and at a central level of government. Policy making power is vested within that institution, or rests in another centralised authority. hESC research is tightly controlled through specific regulatory mechanisms and scientists and researchers must abide by these regulations or face consequences. Negotiations about hESC research governance occur between a variety of actors, stakeholders and citizens and the governance process is open to engagement and participation through many channels. Deliberations that occur within the governance structure are informed by a similar variety of views and perspectives and may be expert-based or lay.
Centralised, technocratic, passive	Oversight of hESC research is centralised within a single regulatory institution and at a central level of government. Policy making power is vested within that institution, or rests in another centralised authority. The mechanisms for overseeing hESC research are passive and scientists and researchers enjoy a large degree of autonomy to conduct research; although they may be restricted by some overarching norms or formal restrictions. Negotiations occur between designated technical experts and policy officials and these people set the context and parameters for any deliberations or discussions. These deliberations are informed by selected types of technical and scientific advice. Engagement and participation is fairly limited and most open to technical or scientific experts and policy officials.
Centralised, technocratic, regulations	Oversight of hESC research is centralised within a single regulatory institution and at a national level of government. Policy making power is vested within that institution, or rests in a similarly centralised authority. hESC research is tightly controlled through specific regulatory mechanisms and scientists and researchers must abide by these regulations or face consequences. Negotiations occur between designated technical experts and policy officials and these people set the context and parameters for any deliberations or discussions. These deliberations are informed by selected types of technical and scientific advice. Engagement and participation is fairly limited and most open to technical or scientific experts and policy officials.
Decentralised, democratic, passive	Oversight of hESC research is primarily through research institutions or at a regional level of government. Policy making power may be dispersed among different government institutions and is not centralised at the national level. hESC research is passively regulated, with overarching institutional, disciplinary or regulatory norms and mechanisms that might guide hESC research, but a large degree of scientific and research autonomy exists. Negotiations about hESC research governance occur between a variety of actors,

	stakeholders and citizens and the governance process is open to engagement and participation through many channels. Deliberations that occur within the governance structure are informed by a similar variety of views and perspectives and may be expert-based or lay.
Decentralised, democratic, regulations	Oversight of hESC research is primarily through research institutions or at a regional level of government. Policy making power may be dispersed among different government institutions and is not centralised at the national level. hESC research is tightly controlled through specific regulatory mechanisms and scientists and researchers must abide by these regulations or face consequences. Negotiations about hESC research governance occur between a variety of actors, stakeholders and citizens and the governance process is open to engagement and participation through many channels. Deliberations that occur within the governance structure are informed by a similar variety of views and perspectives and may be expert-based or lay.
Decentralised, technocratic, passive	Oversight of hESC research is primarily through research institutions or at a regional level of government. Policy making power may be dispersed among different government institutions and is not centralised at the national level. hESC research is passively regulated, with voluntary or overarching institutional, disciplinary or regulatory norms and mechanisms that might guide hESC research, but a large degree of scientific and research autonomy exists. Negotiations occur between designated technical experts and policy officials and these people set the context and parameters for any deliberations or discussions. These deliberations are informed by selected types of technical and scientific advice. Engagement and participation is fairly limited and most open to technical or scientific experts and policy officials.
Decentralised, technocratic, regulations	Oversight of hESC research is primarily through research institutions or at a regional level of government. Policy making power may be dispersed among different government institutions and is not centralised at the national level. hESC research is tightly controlled through specific regulatory mechanisms and scientists and researchers must abide by these regulations or face consequences. Negotiations occur between designated technical experts and policy officials and these people set the context and parameters for any deliberations or discussions. These deliberations are informed by selected types of technical and scientific advice. Engagement and participation is fairly limited and most open to technical or scientific experts and policy officials.

Table B.2: Global policies for hESC research

	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
United States	Federal government, (the NIH), disperses federal research funds (subject to restrictions such as IRB review); Another locus of authority operates within judicial system	State governments have authority to regulate and allocate state-based research funds; All research must adhere to federal standards.	Reliance on bioethics committees and other scientific expertise panels to review not only policy-based decisions, but also scientific procedures themselves.	Citizen input through appointed experts or federal register	Restrictions at federal level on funding for HESC research; No legislative law passed, though several attempted of a 'targeted fix' variety	No specific hESC research oversight of private sector; NAS 'voluntary' research guidelines; Professional codes of practice at voluntary level
Summary and Notes:	Equal distribution between each. Level of centralisation determined by other two dimensions.		Tendency towards expert-based deliberation over democratic and participatory methods of engagement. Sits towards the top of this axis.		Currently no specific prohibitions exist on HESC research except federal funding restrictions. Passive steering side of axis	
	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
United Kingdom	Central regulatory authority	Some institutional oversight once research has been approved.	Decisions on research taken through HEFA that is comprised of experts and lay persons.	Public consultation is integral part of operation of HFEA and its policy decisions	Specific prohibitions are legislated; research activities are heavily regulated, licensed and monitored	Little to no passive steering.
Summary and Notes:	Centralised system at both level of regulatory institution and unitary state government		Both expert-based deliberation and nation-wide public consultations that are more participatory		Research activity has well-defined boundaries and controlled operating procedures	

	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Sweden	General ethical principles underpin HESC policy and were formulated by central government	Oversight at regional research level and through institutional / scientific review boards.	All seven parties of the Swedish Parliament reached consensus on allowing hESC research (although unclear how this was achieved)		Only prohibition is on reproductive cloning	Most scientific research left largely to the market with ethical regulation in place at individual institutions
Summary and Notes:	Would place them towards decentralised institutional oversight of research		Parliamentary consensus seems more based on expert input		Very passive environment with research with boundaries of research set, but otherwise researchers and medical professionals given freedom	
	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Australia	ERLC oversees embryo research licensing	Regulatory enforcement through professional bodies (originally); Individual states can pass their own laws.	ELRC has expert composition with no 'lay' input.	Democratic and participatory input at state level; national public consultations occur.	Specific prohibitions passed by Parliament; Professional standards are codified through law	
Summary and Notes:	Decentralised due to its grounding in professional self-regulation and devolved power to individual states		Appears to take a technocratic approach, both in developing new policies and in composition of advisory bodies		Would place towards middle of axis.	

	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Canada	Centralised regulatory institution has oversight, operates at federal level, individual provinces have little authority		Oversight body has expert-based representation	Wide-ranging public engagement on development of new regulatory structure	Prohibitions on the 'ends' of research, as opposed to the means	
Summary and Notes:	Centralised authority through federal government and newly created Assisted Reproductive Agency of Canada		Due to broad-based public input, tendency towards democratic/participatory engagement		Clearly defined research activity boundaries and tightly controlled operation of research	
	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Germany	Centralised oversight of hESC research		Debate was interest group driven, less participatory		Very tight regulations	
Summary and Notes:	Oversight through legislative bans and strict regulatory controls overseen by central authority and ethics bodies		Technocratic tendencies are very strong, debate was highly politicized		No 'passivity', strict enforcement procedures	
	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Singapore	Centralised government control; Institutional oversight within one regulatory institution		Bioethics Advisory Committee made principle recommendations, but did solicit and consider broad public inputs	No specific participatory engagement except for public consultation by advisory body	Boundaries on research do exist, but at a high level	
Summary and Notes:	Would place on centralised end of axis.		Would place more towards technocratic/expert-based negotiation processes		Within parameters of law, passive control seems to be the tendency with few specific HESC research regulations	

	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Switzerland	Centralised control and oversight through federal acts, legislation and institutional oversight by Federal Department of Health		Basic principles of law developed by Swiss National Advisory Commission on Bioethics;	Electorate vote on whether to allow HESC research	Some prohibitions on types of research, specifically therapeutic cloning	
Summary and Notes:	Would classify this as centralised control of HESC research programmes		Inputs to the commission do not appear to be overtly democratic, but not explicitly technocratic in nature		Due to the fact there are targeted regulations on how research can be conducted, would place them more towards the 'left' on this axis.	
	Institutional Oversight		Processes of Negotiation/Deliberation/Engagement		Mechanisms of Regulation	
	Centralisation	De-centralisation	Technocratic / Expert-based	Democratic / Participatory	Targeted regulations	Passive steering
Italy	Centralised oversight by government agency to enforce legislative restrictions		In case of HESC research, scientific community was not in support of current policy	Some public opinion polls seem to suggest public is generally in favour of HESC research.	Specific legislative bans on all embryo research, including HESC research	On research with adult embryos, no additional controls exist
Summary and Notes:	Centralised control, enforced through law (as under mechanisms)		As current policy was an act of legislation, neither category neatly applies. Certainly does not fall under participatory, and some readings confirm this.		Tendency to use targeted controls, although only recently with case of embryo research. Will need to compare with other case study to see if similar characteristics of this dimension apply	

Annex C – Full Text of Multicriteria Mapping Governance Options

The text below is a replica of that provided to all participants prior to their interviews.

Multi-Criteria Mapping Options

Governance of human embryonic stem cell (hESC) research

This interview is looking specifically at the governance of human embryonic stem cell research (hESC). As governance is a widely used term and can mean different things to different people, I will define how it is being used in the context of this interview.

Governance refers to the entire process of defining, developing, engaging, deliberating, negotiating, establishing, implementing and reviewing the oversight for hESC research. These processes can happen within and between many spheres, for example the public and private, scientific and political, ethical and practical, moral and economical. In other words, governance in this context is about the interactions between these multiple processes that are involved in governing hESC research in today's society.

The following options present different governance scenarios for hESC research that we will discuss and evaluate during our MCM interview. A **summary chart** can be found on page 4 that may help in discerning the key differences between the options. (I will provide a colour copy of this at the interview.) All participants will be asked to evaluate the Core Options. You can also choose to evaluate any of the pre-defined Discretionary Options, or to create your own Additional Options. Further details on the MCM interview and the option definition process are given in the MCM Explanatory Note.

Core Options

1. Detailed centralised oversight

Centralised governance with detailed regulations implemented by an expert statutory body that is empowered by legislature and is informed by occasional public involvement initiatives.

This option is broadly analogous to the present governance of hESC research in the UK, without necessarily leading to the same outcomes. Oversight of hESC research is centralised. Primary legislation passed by a national legislature gives powers of regulatory oversight to a central statutory body that is comprised of various experts and lay representatives. The statutory body implements detailed regulations that arise from the primary legislation and include dedicated approval and licensing processes for hESC research. The main emphasis is on deliberations among experts and policy officials and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC governance framework as a whole make serious provision for deliberations and negotiations that attempt to engage a wide range of interested experts, stakeholders and citizens.

2. Expert-led framework

Devolved ethical, expert-based oversight subject to central general laws.

This option is broadly analogous to the present governance of hESC research in Sweden, without necessarily leading to the same outcomes. Policymaking power rests

with a central legislature, but oversight of hESC research is devolved to regional ethics committees that are comprised equally of appointed experts and lay members. The central legislature defines general laws that guide hESC research, but a high degree of autonomy is afforded to researchers within these parameters. The main emphasis is on deliberations within the expert advisory groups and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC research governance framework as a whole involve deliberations and negotiations among experts, policy officials and interested policy actors, with few, if any, formal public involvement initiatives.

3. Detailed expert oversight

Centralised, expert governance through detailed regulations established by legislature and carried out by central scientific institution.

This option is broadly analogous to the present governance of hESC research in Germany, without necessarily leading to the same outcomes. Policy making and regulatory power is centralised in a national legislature. Oversight of hESC research is delegated to a central research institute of scientific excellence. All hESC research is subject to detailed regulations with dedicated approval and licensing processes. The main emphasis is on deliberations among experts and policy officials and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC research governance framework as a whole involve deliberations and negotiations among experts, policy officials and interested policy actors, with few, if any, formal public involvement initiatives.

4. Devolved authority

Devolved legislative authority subject to central detailed regulations and expert review with occasional public participation.

This option is broadly analogous to the present governance of hESC research in Australia, though not necessarily leading to the same outcomes. Primary legislation at the national level establishes a governance framework for hESC research, but empowers individual devolved jurisdictions to pass further legislation implementing the national framework. Oversight of hESC research is controlled through detailed regulations. There is a centralised expert ethics body that is charged with approval and licensing of all research. The main emphasis is on deliberations among experts and policy officials and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC research governance framework as a whole involve negotiations, deliberations and public involvement among a wide range of interested experts, stakeholders and citizens.

5. Mixed central/devolved

Centralised expert governance with detailed regulation of national public research funds, and a variety of devolved governance frameworks.

This option is broadly analogous to the present governance of hESC research in the United States, though not necessarily leading to the same outcomes. The governance framework is mixed, with both central and devolved components. At a centralised level, hESC research is subject to detailed regulation of national research funds. Voluntary guidelines for hESC research are in place, but are not enforceable by law. At a decentralised level, devolved governance frameworks exist that include detailed regulations or general laws. In all cases, the main emphasis is on deliberations among experts and policy officials and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC research

governance framework as a whole involve deliberations and negotiations among experts, policy officials and interested policy actors, but in some cases make serious provision for public involvement initiatives, primarily through invited comment, open meetings and popular vote (referenda).

6. Ethics-led governance

Centralised, expert governance through general laws with ethical oversight.

This option is broadly analogous to the governance of hESC research in Israel, though not necessarily with the same outcomes. Policymaking power rests with a central legislature that primarily relies on expert ethical guidance. Oversight for hESC research is guided by a national bioethics committee. However, within this general framework, a high degree of autonomy is given to researchers. The main emphasis is on deliberations among experts and policy officials and so may be closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC governance framework as a whole involve deliberations and negotiations among experts, policy officials and interested policy actors.

Discretionary Options

7. Devolved democratic governance

Devolved democratic governance through general laws.

Oversight of hESC research is devolved from the national level to individual jurisdictions. A high degree of autonomy is given to researchers within a broad set of general laws. Laws are set and interpreted by individual jurisdictions. Both the setting of laws and their interpretation are subject to serious provision for deliberations and negotiations that include significant public involvement initiatives involving a wide range of experts, stakeholders and citizens.

8. Centralised democratic governance

Centralised democratic governance through general laws.

Oversight of hESC research is centralised. Primary legislation gives powers of oversight of hESC research to a central statutory body. A high degree of autonomy is given to researchers within a broad set of general laws. These laws are set by a national legislature and interpreted by a central statutory body. Both are subject to serious provisions for deliberations and negotiations that include significant public involvement initiatives involving a wide range of experts, stakeholders and citizens.

9. Centralised regulatory authority

Centralised detailed regulation by expert statutory body subject to oversight by legislature.

This option is broadly analogous to the newly established system of governance in Canada, though not necessarily with the same outcomes. Oversight of hESC research is centralised, with primary authority resting with the legislature and regulatory oversight devolved to a statutory body composed of various expertises. The statutory body enforces detailed regulations with dedicated processes for licensing and approval of research. The main emphasis is on deliberations among experts and policy officials and so may be relatively closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC research governance framework as a whole may make provision for public involvement initiatives, but at present involve deliberations and negotiations among experts, policy officials and interested policy actors.

		Centralisation?	Laws and Regulations?	Types of Deliberations?
Core Options	Detailed centralised oversight (United Kingdom)	Central legislation Approval by central statutory body	Detailed regulations for approval and licensing	Expert-based with serious provision for public involvement
	Expert-led framework (Sweden)	Central legislation Approval by devolved regional ethics committees	General laws, ethics approval required	Expert-based and ethics review
	Detailed expert oversight (Germany)	Central legislation Approval by central research institute	Detailed regulations for approval and licensing	Expert-based
	Devolved authority (Australia)	Centralised and devolved policies Approval by central expert ethics body	Detailed regulations for approval and licensing	Expert-based with public involvement
	Mixed central / devolved (United States)	Centralised and devolved policies Approval by mix of central and devolved frameworks	Detailed regulation of central public funding, Mix of detailed regulations and general laws at devolved level	Expert-based with provision for public involvement
	Ethics-led governance (Israel)	Central legislature Approval by research institutions	General laws within an ethical framework	Expert-based and ethics review
Discretionary Options	Devolved democratic governance	Devolved legislation	General laws	Public involvement
	Centralised democratic governance	Centralised oversight	General laws	Public involvement
	Centralised regulatory authority (Canada)	Central legislature Approval by central statutory body	Detailed regulations for approval and licensing	Expert-based

Centralised	Detailed regulations	Public involvement
Mixed Centralisation	Mix of general and detailed regulations	Mix of deliberations
Decentralised	General laws	Expert based

Annex D – Example emails and background information provided to participants

Example introductory email to new contact

The email below is an example of one sent to a new contact who either was referred by a previous participant or I had identified through research.

Dear Dr Smith¹⁵⁷,

My name is Molly Morgan and I am a Ph.D. student at the Science and Technology Policy Research Institute (SPRU) at the University of Sussex in the United Kingdom. I am writing today to invite you to participate in an interview for my doctoral research study which is entitled 'Governing the constructs of life'. It is a comparative study looking at how 'good' governance for human embryonic stem cell (hESC) research is thought about and defined by different groups of stakeholders in the US and the UK

I have been speaking to many leading experts on both sides of the Atlantic for this research and all have found it very interesting and timely. It is especially important, however, when it comes to the US context of this research that I capture perspectives within different states. As your organisation¹⁵⁸ is an active voice in the wider discussions about hESC research, especially in your state¹⁵⁹, it is a crucial point of view to include in my research. Below you will find a brief introduction to my study, as well as some details about the interview itself.

As mentioned above, I am interviewing prominent policy makers, medical professionals, scientists, and other expert stakeholders with particular interests in the area of hESC research and asking them to evaluate different governance and regulatory frameworks that might be used to govern the research. The interviews are conducted using an interactive appraisal technique entitled Multicriteria Mapping (MCM). MCM provides a way for individuals to appraise different possible scenarios for a complex issue. As I am asking participants in this study to evaluate different governance frameworks for hESC research, I am most interested in the views and perspectives that each participant articulates and uses during the evaluation process.

The interview times can vary, but most take about two hours. I will be in the your area in the latter half of would be happy to schedule a time that was most convenient for you. I hope you will be able to accept my invitation, however I appreciate you have many demands on your time. If you are unable to participate, or feel there is another individual within your organisation who is more appropriate to contact, I would be grateful for your suggestions. Thank you in advance for your time in considering this request and I look forward to hearing from you.

¹⁵⁷ This name, and others below, are fictional.

¹⁵⁸ The organisation was referred to by name at this point in the email, but has been made generic here.

¹⁵⁹ If the individual was based in an organisation in a particular state or region of the country which was relevant to why they were contacted to participate in the interview, this was made known here.

Example introductory email to MSc participant

The email below is an example email of the kind sent initially to those who participated in my MSc research in 2004.

Dear Ms. Smith,

If you will recall, we met in June 2004 after you kindly agreed to be a participant in my Master's dissertation research. That research was looking at different options for regulating stem cell research in the US. We met at your office in Washington, DC where I interviewed you using an interactive, computer-based technique entitled Multi-Criteria Mapping (MCM). The thesis was very well received and I won an award for the most outstanding MSc dissertation of my year, so thank you again for your participation in that research.

After spending a few years working in science policy for government departments in both the United Kingdom and the United States, I am now back at the University of Sussex pursuing my Doctorate in Science and Technology Policy. My doctoral research is looking at how notions of 'good' governance differ in the US and the UK for areas of challenging, and often contested, 'human' biotechnology research. At this time I am focusing on medical biotechnologies, specifically human embryonic stem cell (hESC) research. As this research is built on ideas first explored in my Master's thesis, I wanted to invite you to participate and provide your expert input to this important and topical area of research. Your views and inputs were invaluable to my previous work, and would continue to be so in this doctoral study.

As before, the interviews will use the unique format of MCM to evaluate different governance options for hESC research. When I was conducting my Master's research, I was fortunate enough to interview distinguished and prominent people with an active interest in the area of stem cell research such as yourself¹⁶⁰. My doctoral research will again seek the views of prominent scientists, advocates and representatives from different stakeholder groups in the US, and similarly in the UK.

I hope you are able to participate in this research and share your expert views and opinions. I will be conducting interviews in your area during the month of January in 2008 and would arrange a time and location that was most convenient for you.

Thank you in advance for taking the time to consider this invitation. I would be happy to send through any additional information should you need it. I look forward to hearing from you.

Background information provided to participants before the interview

The text below is identical to that provided to participants prior to their interview. It was accompanied by a cover letter which reminded them of the time and

¹⁶⁰ This sentence contained the names of people who had participated in my MSc research and who had agreed to have their names shared at that time. These have been deleted for the purposes here.

date of their interview and asked that they review the material in the information pack prior to our meeting. The documents were sent in hard copy and by email. A copy of the cover letter is presented first.

Dear Professor Smith,

Thank you for agreeing to participate in my doctoral research project. Our interview is scheduled for Tuesday, 03 June 2008 at 2:30pm. We will be meeting at your office at the address above. During the interview we will be making use of my laptop computer, so it would be best if we could sit side by side at a table or desk. Please let me know as soon as possible if this will pose a problem or if you need to make any changes to the arranged time.

This information pack contains two background documents about the MCM interview: 1) the MCM Explanatory Note and 2) MCM hESC Governance Options. The first explains the MCM interview process and the second outlines the governance options for hESC research that we will be discussing and evaluating during the interview.

I would encourage you to read through at least the summary section of the Explanatory Note and try to familiarize yourself with the MCM hESC Governance Options. This will help to make the interview more efficient, however do not worry if anything is unclear as we will be able to go over everything on the day.

If you have any questions prior to the interview I will be happy to answer them. Thank you again and I look forward to meeting you next Tuesday.

*Kind regards,
Molly Morgan*

Multicriteria Mapping Interview Background Documents

The following section is a replica of the 'explanatory note' provided to participants prior to their interviews

Multicriteria Mapping Explanatory Note: The MCM process explained

This explanatory note provides an introduction to the MCM interview process. The Summary on this page gives a brief overview of each of the MCM stages. Further detail and a worked example of an MCM interview is provided in the additional pages.

Summary

Multi-Criteria Mapping (MCM) is an interactive, decision analysis technique that provides a way of appraising a series of different options, or possible ways forward, for a complex issue. It helps individuals to explain their beliefs and views about a complex or controversial issue in a structured and systematic way.

An MCM interview has four stages. The information generated during the MCM interview is recorded using a software programme, so we will be working with my laptop computer. If this poses a problem, please let me know as soon as possible.

Stage 1 – defining the options: There are three types of MCM options that we will come across during the interview: Core Options, Discretionary Options and Additional Options. I have already defined 6 Core Options and 3 Discretionary Options for this interview. These are explained in detail in the MCM Options note included in the information pack. It is important you are familiar with these options as we go through the interview, so in this stage we will go over the different options and clarify any that are unclear. You may also wish to define Additional Options to evaluate, which can be done at this time. Further information about Additional Options is provided below.

Stage 2 – defining criteria: In this stage, you will be asked to define 6-8 criteria that you will eventually use to evaluate the options from stage 1. *Criteria* are the different ideas, beliefs, technical judgements or opinions you might use when considering what you think about each option. Criteria are the individual thoughts that might occur to you were someone to ask, *what do you think of option x and why?* We will go over some examples of criteria at the beginning of the interview.

Stage 3 – scoring the options: During this stage, you will evaluate each option according to how well you deem it to 'perform' under each of the criterion you defined in stage 2. In other words, you are evaluating the extent to which each option would allow an individual criterion to be optimally fulfilled. This is the most detailed part of the MCM process, but also one of the most important for the final analysis.

Stage 4 – weighting the criteria: This stage is different from scoring, where you were evaluating each option. In the weighting stage, you will be asked to evaluate the relative importance of each criteria *against each other*. Thus, if Criteria A is twice as important to you as Criteria B, you will be able to reflect this here. These weightings, together with the scores, will determine the final performance rankings of each of the options you have evaluated.

The remainder of this note describes each stage in further detail. A worked example of the MCM stages is provided in the final pages.

Stage 1 – Defining the options

The options represent a range of possible governance scenarios for hESC research. MCM uses three types of options: core options, discretionary options and additional options. The Core Options are evaluated by all participants. Discretionary Options have also been pre-defined and you may choose to evaluate some of these, as well. If you feel that none of the existing options capture an aspect of governance that you feel is important to discuss, you can then define Additional Options to evaluate.

For the present exercise, I have defined six Core Options and three Discretionary Options. If possible, please familiarise yourself with the Core Options and give some thought to any Discretionary or Additional Options you will want to evaluate. A detailed description of the core options is included in this information pack, but the headlines are listed here:

Core Options

10. **Centralised governance with detailed regulations implemented by an expert statutory body that is empowered by legislature and is informed by occasional public involvement initiatives.**
11. **Devolved ethical, expert-based oversight subject to central general laws.**
12. **Centralised, expert governance through detailed regulations established by legislature and carried out by central scientific institution.**
13. **Devolved legislative authority subject to central detailed regulations and expert review with occasional public participation.**
14. **Centralised expert governance with detailed regulation of federal public research funds, and a variety of devolved governance frameworks.**
15. **Centralised, expert governance through general laws with ethical oversight.**

Discretionary Options

16. **Devolved democratic governance through general laws.**
17. **Centralised democratic governance through general laws.**
18. **Centralised detailed regulation by expert statutory body subject to oversight by legislature.**

Stage 2 – Defining the criteria used to evaluate the options

If you were asked the question, “What do you think of this option and why?”, criteria are the thoughts you might consider when answering. Criteria are the different ideas, assumptions, expert opinions, judgements and issues of importance you may wish to use to evaluate the different options.

We will go over some examples of criteria for this specific case of hESC research at the beginning of the interview. However, please jot any thoughts down prior to our meeting if you have them. You will be asked to explain what you mean by each criteria and why you have chosen it, so it is important to have a clear idea of the criteria you are using and the differences between them. For purposes of time and efficiency, I recommend you restrict yourself to six criteria or less.

Stage 3 – Scoring

Due to the complex nature of scoring and the discussion that ensues, this is the most time consuming part of the MCM process. It is important to understand how it works.

The criteria from Stage 2 will be used to evaluate the different governance options. This is done by giving a score to each option as you deem it to ‘perform’ under each criterion. This value is entirely up to you to determine. Often technical judgements, for example costs or other quantifiable information, are used to assign a score. The scores are expressed using a scale, for example from one to ten or one to one hundred. The higher the number, the better the performance of the option under a particular criterion.

There are two caveats to scoring. The first occurs when you are uncertain about an option’s performance. For example, you may think the performance depends on certain social or political circumstances, or other assumptions that need to be reflected. The MCM process allows you to express this uncertainty through a high and low score for each option. One score reflects the most optimistic end of your judgement of likely performance, while the other score reflects the most pessimistic end.

The second caveat applies when you have defined a criterion that reflects an issue of principle. These types of criteria do not lend themselves to scoring. Instead, these criterion simply allow you to state whether an option is acceptable or not under that criterion. In this case, you can simply define an option as either acceptable or unacceptable under that ‘criterion of principle’.

As you proceed with your scoring, I will ask you to clarify the reasons for your decisions of the relative performance of the options under the criterion. I am interested in the justifications for your scores and will use these for comparison in my analysis later on.

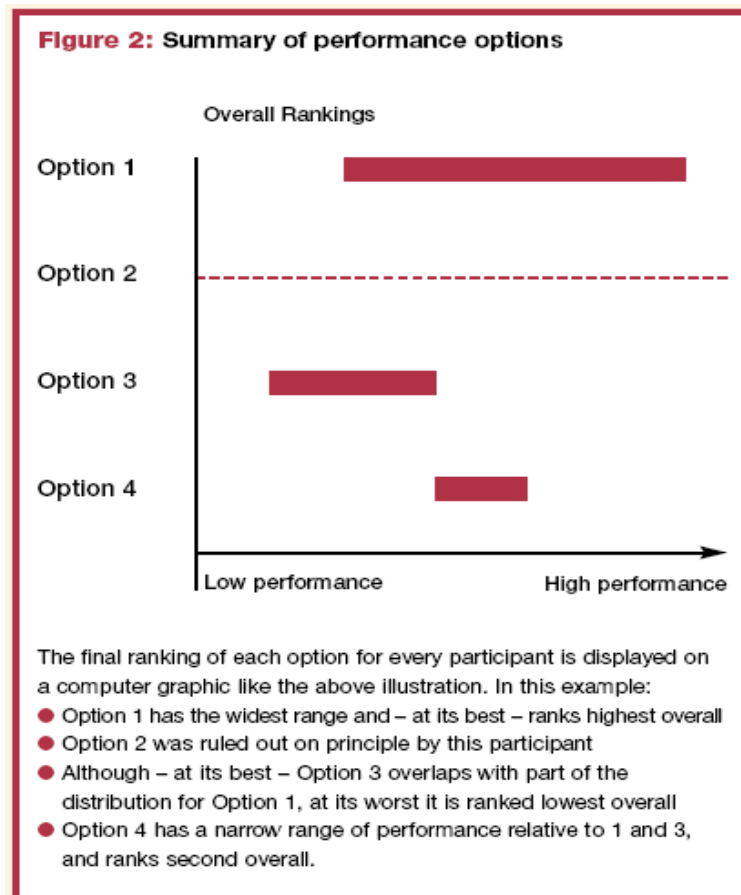
Stage 4 – Weighting

This stage involves assigning a relative order of importance to the criteria. One way to think about this is to decide what number of points from a total of 100 you would assign to each criterion. If one criterion is half as important to you as something else, it will be assigned half the number of points.

Weighting is very different from scoring. Scores reflect relatively technical judgements about the performance of options under individual criteria. Weights are essentially subjective judgements about the relative importance of the different criteria themselves. Where you have identified a criterion as being an issue of principle, an option is either acceptable or not. For this reason, issues of principle are not a part of the weighting exercise.

The Outcome

At the end of the process the software will generate a simple chart of how each option performs overall, taking into account all your criteria scores and weightings. Embedded in the chart are reflections of your criteria choices, technical judgements of the option performance, uncertainties, and priorities concerning the relative importance of each criterion. The final MCM chart will look something like the one below:



We will use this chart to discuss how this picture of relative performance fits with your general expectations and beliefs about the governance frameworks for hESC research. You will also be able to investigate what happens if the weightings you gave are changed. This may aid you in settling on a pattern of weightings which best reflects your beliefs and point of view.

A WORKED MCM EXAMPLE – THE CASE OF ENERGY GENERATION

The Government wishes to take advice over its policy priorities concerning which electricity generating options to encourage and which to discourage. One specialist undertook an MCM exercise as a means of offering her advice.

Stage 1 – Options

The 3 core options were:

1. Nuclear power
2. Coal burning
3. Wind energy

The specialist being interviewed also added 'gas generation' to the list because of the importance of gas to current energy production.

Stage 2 – Criteria

The specialist decided upon the following criteria:

- Worker safety: the incidence of fatal or serious injuries or disease across whole 'fuel cycle' (from mining to waste disposal)
- Public health: incidence of adverse public health effects due to emissions, wastes, or accidents (excluding global warming effects)
- Contribution to global warming: equivalent carbon production taking into account whole fuel cycle and material and energy use during construction
- Electricity cost: taking account of capital costs, fuel cycle costs and waste management costs under prevailing market conditions

An additional criterion introduced an issue of principle:

- Maximum accident: a limit on the maximum extent of acceptable damage arising from a single possible accident. Set at costs in excess of \$25 billion or total committed public mortality in excess of 10,000 people.

Stage 3 – Scoring

The specialist then scored each criterion under each option. A high and low score was given when it was uncertain how an option might perform. A scale of 1-10 was chosen, with 10 being good and 1 being bad. The specialist explained some her scoring processes this way:

"Worker safety in nuclear power is generally very good, but there can be accidents. However, these are very rare. I'd score worker safety for nuclear as 6-8. Worker safety for coal is not so good. Mines can collapse and many miners can be killed. I'd score worker safety as 4-7 for coal..."

"Nuclear power doesn't contribute to global warming unless the energy used in their construction is produced by burning carbon. Therefore, they both score between 9 and 10. Coal is the worst and so scores 1-3. Gas is somewhere in between, scoring 3-5..."

"Nuclear power is the only option that presents a risk of a type of disaster that, although very unlikely, is beyond the threshold of what is acceptable to society, so it is ruled out on principle in relation to maximum accidents."

Stage 4 – Weighting

The specialist first ranked the criteria, putting worker safety top, public safety second, cost third, and then global warming.

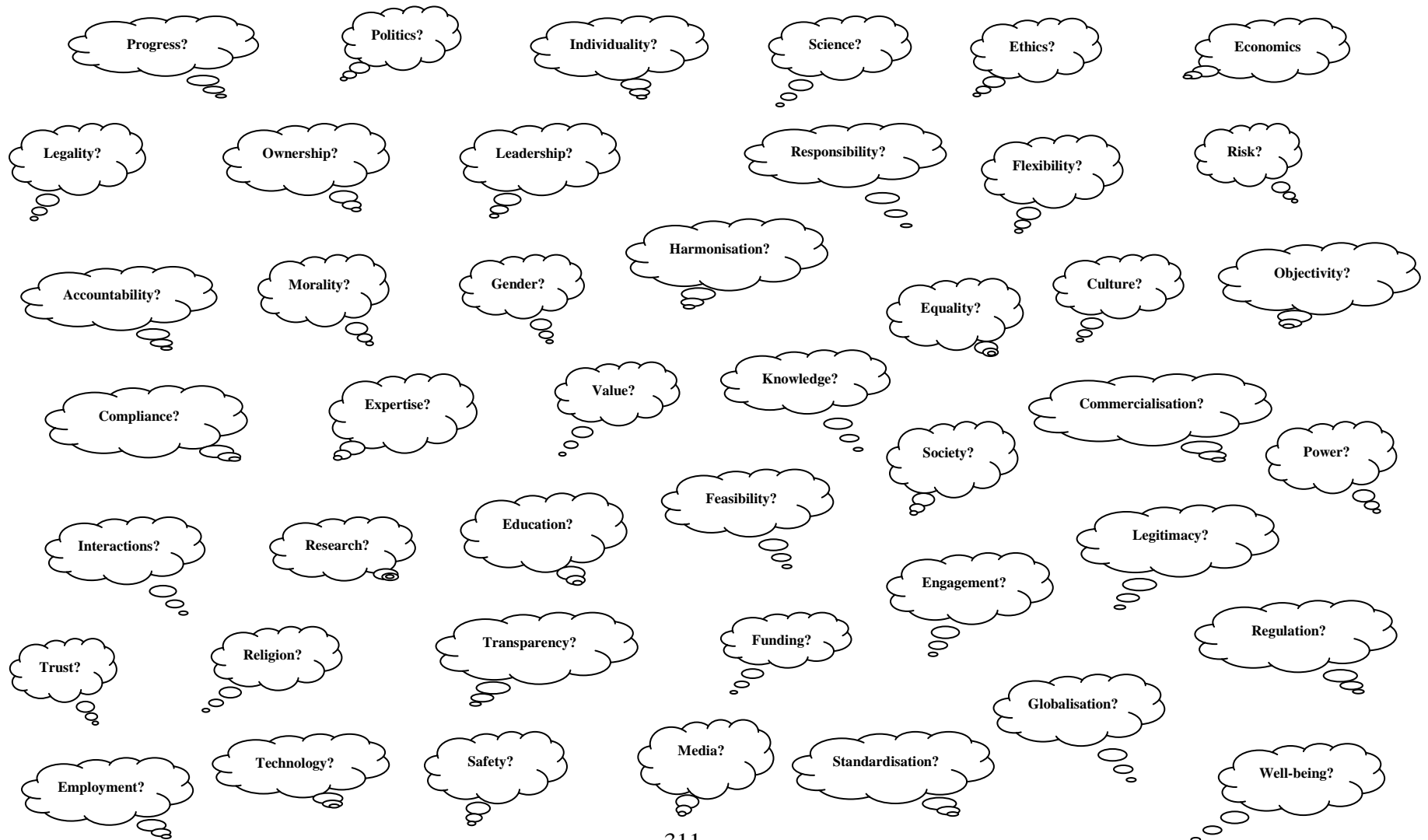
She then thought about how much more important one was than another – to do this she thought about how 100 'importance points' would be shared between them. The specialist thought worker and public safety were almost equally important and gave worker safety 40 and public health 35 points. Cost was thought to be half as important at 18 points, and, because she felt there was little that could be done about global warming, gave it a score of 7.

The Outcome

As a result of all these inputs, the final chart shows wind energy generally performing best overall, varying between 63 and 97 points on the ranking scale. Gas generation ranks second (between 30 and 76), overlapping with the lower end of the wind scale rank. Coal burning comes third, ranking between 8 and 57 - presenting quite a large overlap with gas, but none at all with wind. Nuclear power was ruled out under the 'maximum accident' rule.

‘Thought Bubble’ diagram given to participants during the MCM interview

THIS LIST OF ISSUES IS PROVIDED TO HELP YOU THINK ABOUT THE CRITERIA IN MORE DETAIL.
THESE ARE ONLY PROMPTS, YOU DO NOT HAVE TO USE ANY OF THEM.
IF YOU WOULD LIKE TO USE THESE PROMPTS, PLEASE DEFINE THEM IN A WAY THAT IS MEANINGFUL TO YOU.



Annex E – Multicriteria Mapping Interviewee Codes

Table E.1 – Multicriteria Mapping Interviewee Codes

Interviewee	Perspective	Reference Code in Thesis Text
Member of a genetic rights advocacy group	Advocates	UK policy opposition 1
Member of a reproductive ethics group	Advocates	UK policy opposition 2
Member of a Multiple Sclerosis patient advocacy group	Advocates	UK patient advocate 3
Member of a cancer patient advocacy group	Advocates	UK patient advocate 4
Member of a genetic disease patient advocacy group	Advocates	UK patient advocate 5
Member of an organisation concerned with issues about biotechnology and society	Advocates	UK policy opposition 6
Member of an Alzheimer's disease patient advocacy group	Advocates	UK patient advocate 7 ¹⁶¹
Member of a medical religious advocacy group	Advocates	UK policy opposition 8 ¹⁶²
Member of a Parkinson's disease patient advocacy group	Advocates	US patient advocate 1
Member of an organisation concerned with issues about biotechnology and society	Advocates	US policy opposition 2
Advisor to multiple patient and science advocacy groups	Advocates	US policy advocate 3
Member of a juvenile diabetes patient advocacy group	Advocates	US patient advocate 4
Member of a reproductive medicine advocacy group	Advocates	US patient advocate 5
Member of a Republican party woman's advocacy group	Advocates	US policy advocate 6
TOTAL	12 (14)	
Member of a government bioethics advisory body	Bioethicists	UK bioethicist 1
Bioethicist for various foundations and government advisory bodies	Bioethicists	UK bioethicist 2
Bioethicist at a UK university	Bioethicists	UK bioethicist 3
Bioethicist for a medical professional body	Bioethicists	UK bioethicist 4

¹⁶¹ This participant did not complete a full interview, so they are not included in much of the analysis and presentation of ranking charts.

¹⁶² As above, this participant did not complete a full interview, so they are not included in much of the analysis and presentation of ranking charts.

Interviewee	Perspective	Reference Code in Thesis Text
Bioethicist at an American university	Bioethicists	US bioethicist 1
Bioethicist at an American university	Bioethicists	US bioethicist 2
Bioethicist for a biotechnology industry group	Bioethicists	US bioethicist 3
Bioethicist at an American university	Bioethicists	US bioethicist 4
Bioethicist for a policy think tank	Bioethicists	US bioethicist 5
TOTAL	9	
Chief Executive of a stem cell technology company	Industry and Professional	UK industry executive 1
Chief Executive of a stem cell (start-up) technology company	Industry and Professional	UK industry executive 2
Research Manager and Vice President of a stem cell technology company	Industry and Professional	UK industry executive 3
Director of a professional stem cell network	Industry and Professional	UK professional body 4
Research manager of a stem cell foundation	Industry and Professional	UK professional body 5
Director of a professional stem cell network	Industry and Professional	UK professional body 6
Vice President for regenerative medicine of a large life sciences technology company	Industry and Professional	US industry executive 1
Vice President for business development of a stem cell technology company	Industry and Professional	US industry executive 2
Director for federal affairs of a medical college professional body	Industry and Professional	US professional body 3
President of a stem cell (start-up) technology company	Industry and Professional	US industry executive 4
Director of a stem cell foundation	Industry and Professional	US professional body 5
President of a technology licensing office of an American university	Industry and Professional	US industry executive 6
TOTAL	12	
Research manager of a national funding body	Policy-makers and Regulators	UK policy-maker 1
Policy-maker for a government department	Policy-makers and Regulators	UK policy-maker 2
Policy-maker in a national policy-making and funding body	Policy-makers and Regulators	UK policy-maker 3
Member of a national regulatory body for stem cell research	Policy-makers and Regulators	UK regulator 4
Director of a national policy body	Policy-makers and Regulators	US policy-maker 1
Director for regulation for a state active in stem cell research	Policy-makers and Regulators	US regulator 2

Interviewee	Perspective	Reference Code in Thesis Text
Research manager of a national policy-making and funding body	Policy-makers and Regulators	US policy-maker 3
Regulatory advisor for a state active in stem cell research	Policy-makers and Regulators	US regulator 4
Policy-maker in a state active in stem cell research	Policy-makers and Regulators	US policy-maker 5
Policy-maker in a US state active in stem cell research	Policy-makers and Regulators	US policy-maker 6
Policy-maker in US state active in stem cell research	Policy-makers and Regulators	US policy-maker 7
Policy-maker in a US state active in stem cell research	Policy-makers and Regulators	US policy-maker 8
TOTAL	12	
Embryologist at a UK university	Laboratory-based scientists	UK scientist 1
Stem cell scientist at a UK university	Laboratory-based scientists	UK scientist 2
Retired professor of genetics and biochemistry at a UK university and hospital	Laboratory-based scientists	UK scientist 3
Stem cell scientist working in the laboratory of a stem cell company	Laboratory-based scientists	UK scientist 4
Stem cell scientist at a UK university	Laboratory-based scientists	UK scientist 5
Stem cell scientist at a UK university hospital	Laboratory-based scientists	UK scientist 6
Stem cell scientist at a UK university	Laboratory-based scientists	UK scientist 7
Retired professor of genetics and biochemistry at a US university	Laboratory-based scientists	US scientist 1
Stem cell scientist at a US medical school	Laboratory-based scientists	US scientist 2
Stem cell scientist at a US medical school	Laboratory-based scientists	US scientist 3
Stem cell scientist at a private research institute	Laboratory-based scientists	US scientist 4
Stem cell scientist at a US university	Laboratory-based scientists	US scientist 5
TOTAL	12	

Annex F – Basic summary of Multicriteria Mapping interview findings

Basic summary

The following sections provide a basic overview of some of the key points relating to how MCM was used during the interviews. We will first discuss the definition of additional options that were defined by 3 interviewees. We will then look at the definition and use of criteria. The three criterion of principle that were defined are presented, as well as a brief summary of the use of the bubble handout sheet. The final section of this Annex presents all the individual performance rankings across the 57 MCM interviews.

Additional options defined during the interviews

The following ‘additional options’ were defined by interviewees:

1. Centralised, expert governance through general laws with ethical oversight (UK Scientist 2).

Policymaking power rests with a central legislature, but they do not legislate on specifics of research. National ethics committee with statutory power would approve the research. Basically this is the HFEA without government interference.

Notes: that relies primarily on expert ethical guidance. Oversight for hESC research is by a national bioethics committee that approves all hESC research. However, within these general laws, a high degree of autonomy is given to researchers. The main emphasis is on deliberations among experts and policy officials and so may be closed to perspectives not represented on expert advisory groups. Periodic changes to the hESC governance framework as a whole involve deliberations and negotiations among experts, policy officials and interested policy actors.

2. Centralised representative governance with local oversight and implementation (US policy-maker 8).

Centralised policy-making body empowered by legislation with a variety of different representation and/or expertise, establishing general, enforceable standards with institutional or shared oversight and implementation. Oversight mechanism is through contract provisions as opposed to regulations. Meetings of the body are open to the public and discussions and decisions are available to the public via the internet.

Notes: The body is providing input into the policies. Leaves out the enforcement mechanism of the board, but is sort of assumed.

3. Centralised democratic governance through general laws and institutional oversight (US policy-maker 5 and US policy-maker 6).¹⁶³

Oversight of hESC research is centralised. Primary legislation gives powers of oversight of hESC research to a central statutory body. These laws are set by a national legislature and interpreted by a central statutory body. The central body establishes a schema that institutions have to enforce. Approval is by a research institution involving approval by an IRB/ESCRO type of committee. A high degree of autonomy is given to researchers within a broad set of general laws. The institutional oversight and setting of regulations by a central statutory body are subject to serious provisions for deliberations and negotiations that include significant public involvement initiatives involving a wide range of experts, stakeholders and citizens.

The evaluations of these options and their final rankings can be found in the individual performance ranking summary charts given in the final section of this Annex.

Summary of criteria use

Criteria definition

In Chapter 4 we introduced the use of the ‘bubble’ sheet as a guide for the participants to use during the criteria definition stage. This sheet can be found in Annex D, above. In total, 93 criteria out of the total 310 criteria defined and evaluated in the MCM interviews were based on a ‘bubble’ or group of bubbles from the prompt sheet. These 93 criteria were defined by 25 individuals. Therefore, under one-third of all criteria were defined using the bubbles as a guide and under half of the individuals defined all or some of their criteria from the prompt sheet (14 participants defined all or all but one of their criteria using only the prompt sheet).

In Chapter 4 we also discussed the various stages of preparation different interviewees might have undertaken prior to the interview. Sixteen participants made notes prior to the interview and between them 81 criteria were defined prior to the actual interview commencing.

Criterion of principle

Three criteria of principle were defined over the course of the MCM interviews by two individuals. Two screenshots of the MC Mapper software are shown below

¹⁶³ This option was defined by two individuals who participated in an interview together, but had different scores for options in places and had different weightings.

relating to the two stages specific to criterion of principle. In the first, the criterion of principle are shown as diamond shapes in the upper left-hand box. In the second figure, the participant has ruled out an option on the basis of it violating one of her criterion.

The three criterion of principle that were defined by the two participants were defined as follows (definitions are paraphrased by the author):

1. *Representation (UK scientist 4): There needs to be full and appropriate public representation within the governance framework. Those options that don't have public involvement won't be acceptable.*
2. *Alignment to the laws of the country (UK scientist 4): Needs to align with laws and legal code that already exist in the country. If you're choosing to set about stem cell research then it's important to abide by what is there in the country already.*
3. *No influence of religion (US patient advocate 5): Religion should not influence the governance framework in any way.*

Only the first criterion of principle was used to rule out an option. The participant concluded that because the detailed expert oversight option did not have any provision for public involvement within the framework that it violated her principles in this way.

Figure F.1: Screenshot of criterion of principle

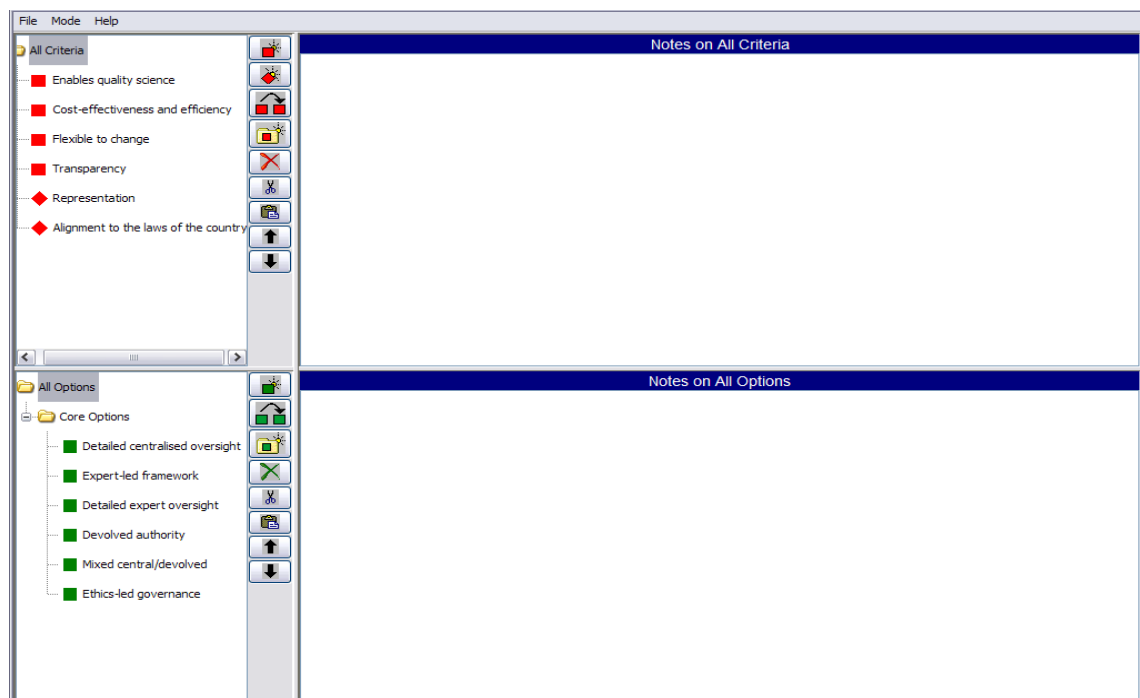
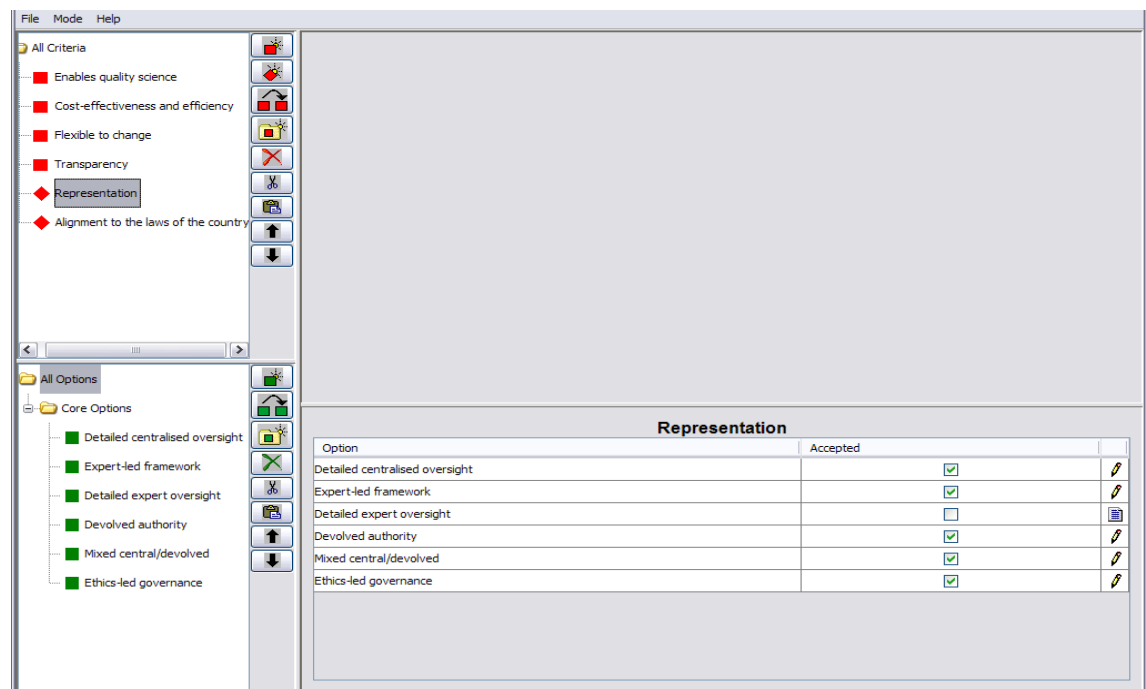


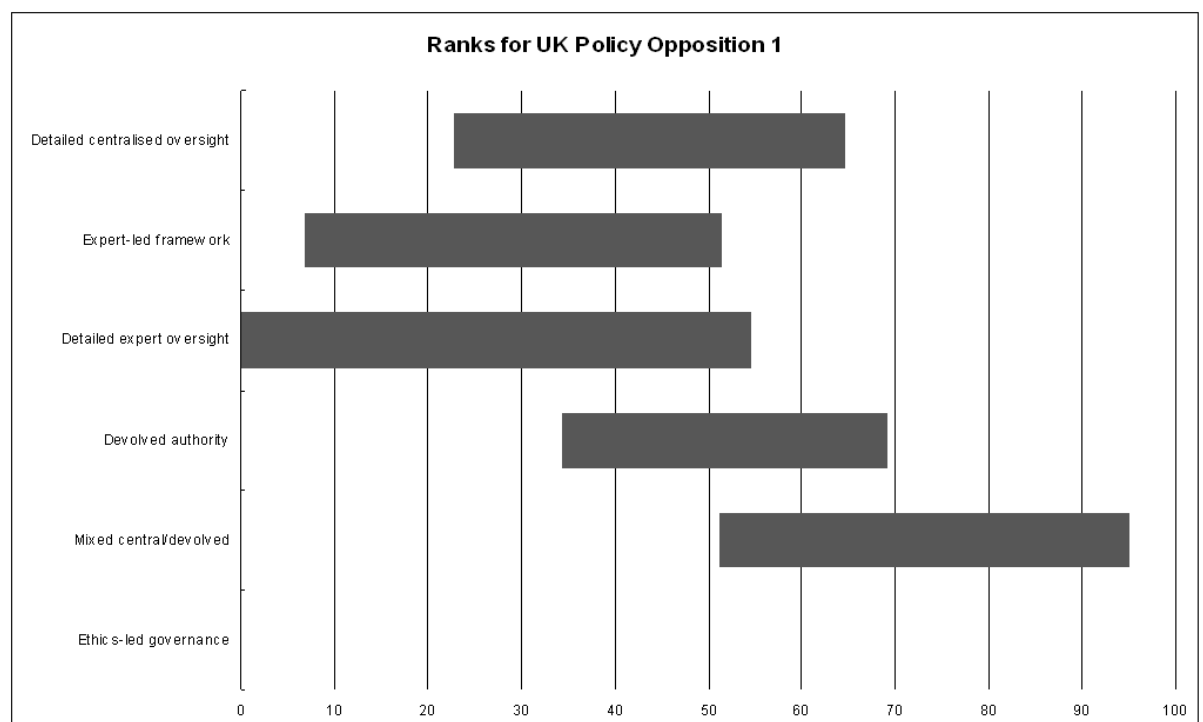
Figure F.2: Screenshot of participant ruling out an option based on violation of criterion of principle

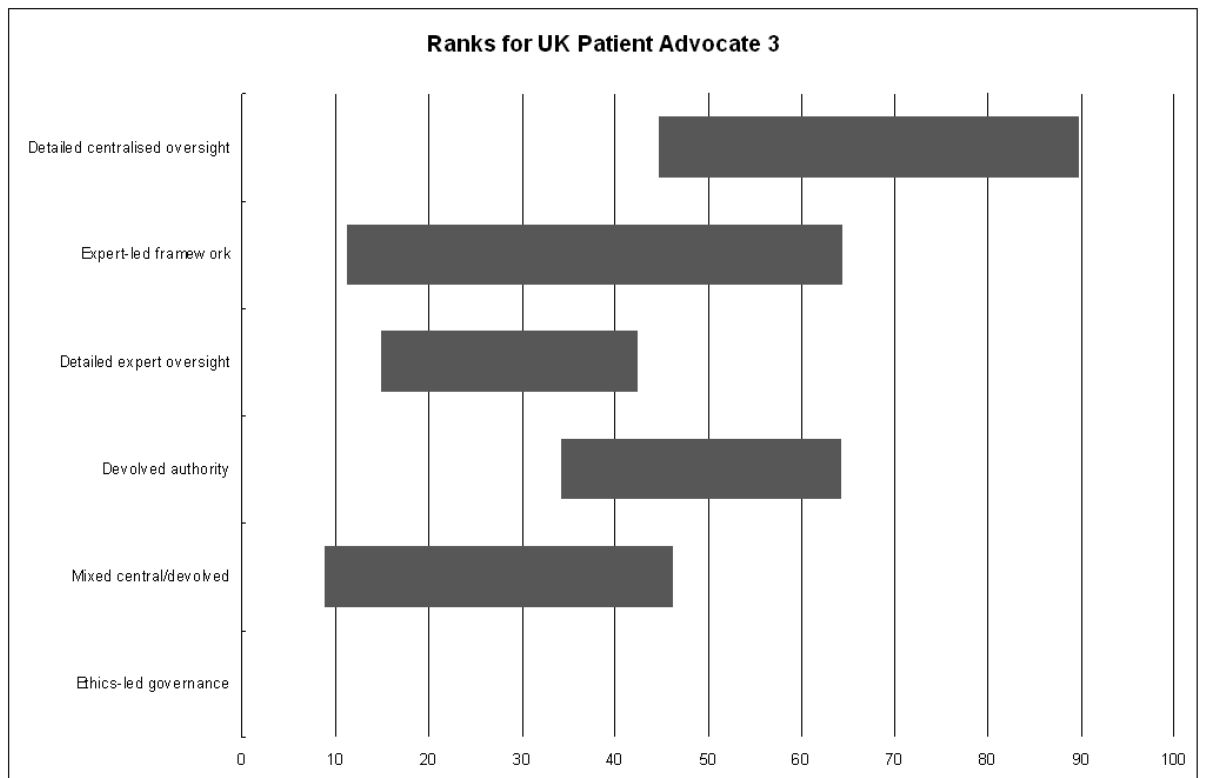
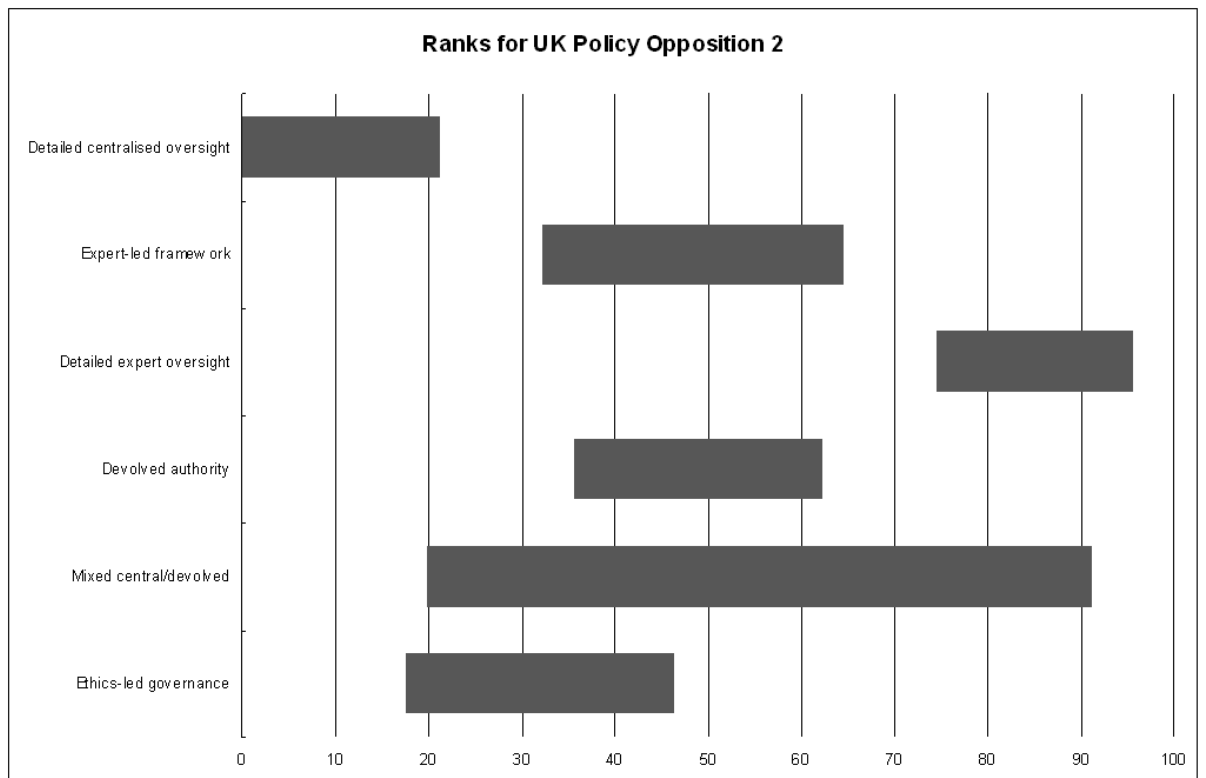


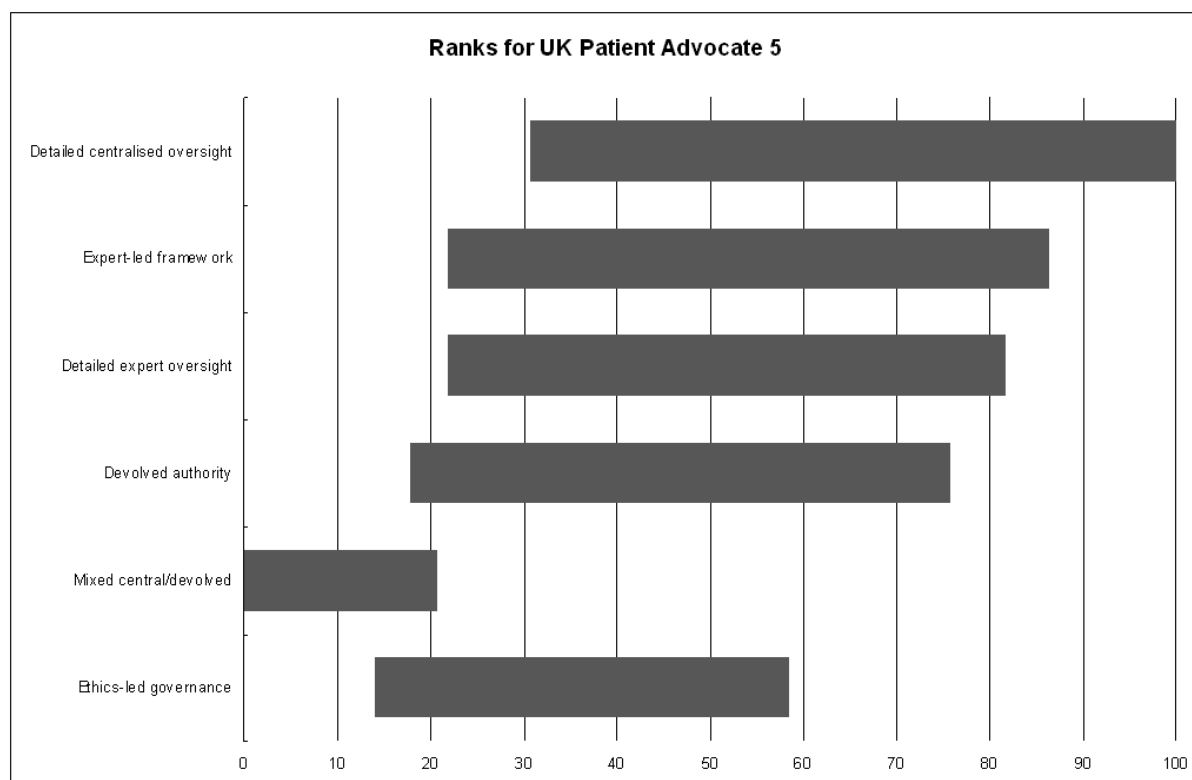
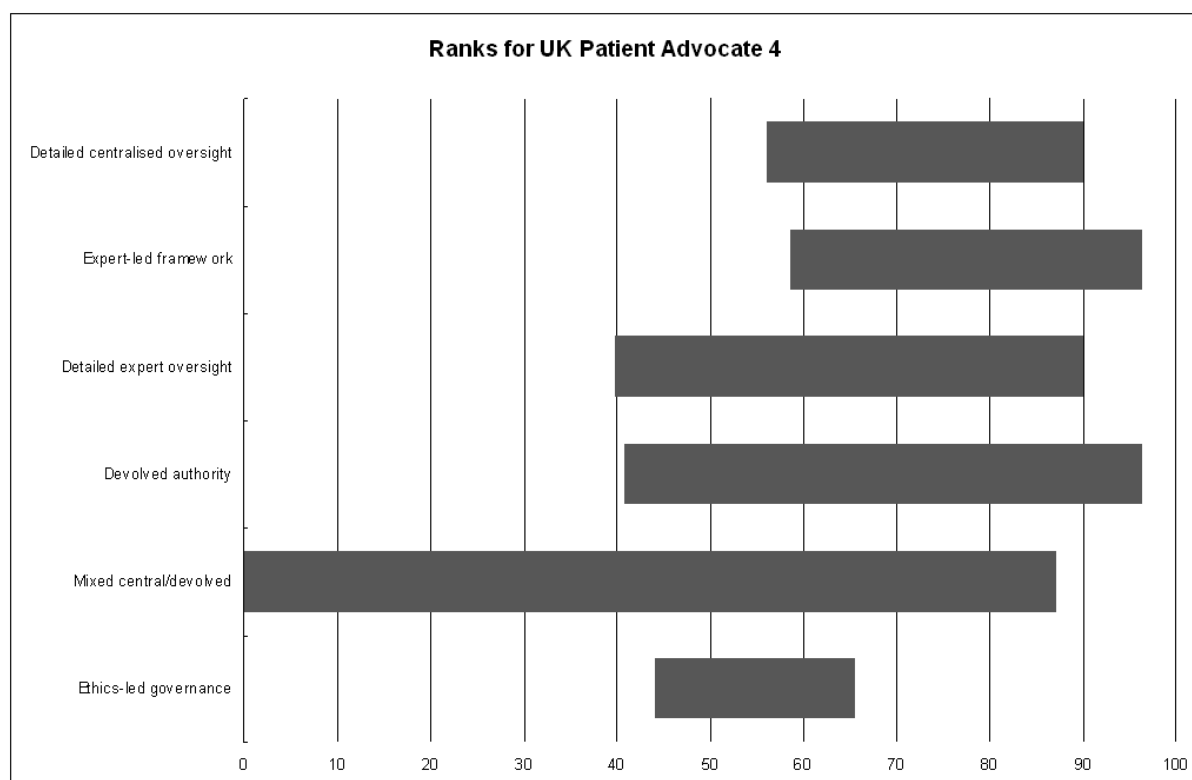
Individual Participant Ranking Charts

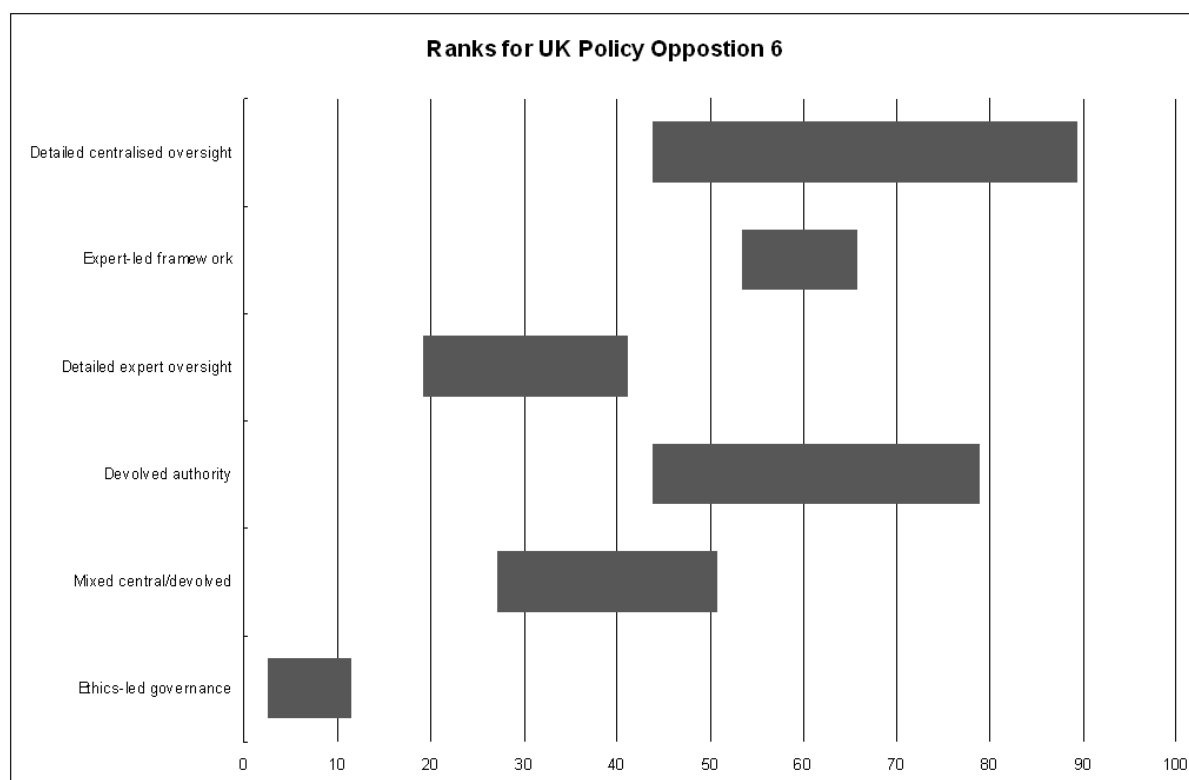
In the following pages, the final ranking charts of each individual who participated in the MCM interviews are shown. Individuals are coded according to the table provided in Annex E.

Ranks for UK Patient and Policy Advocates

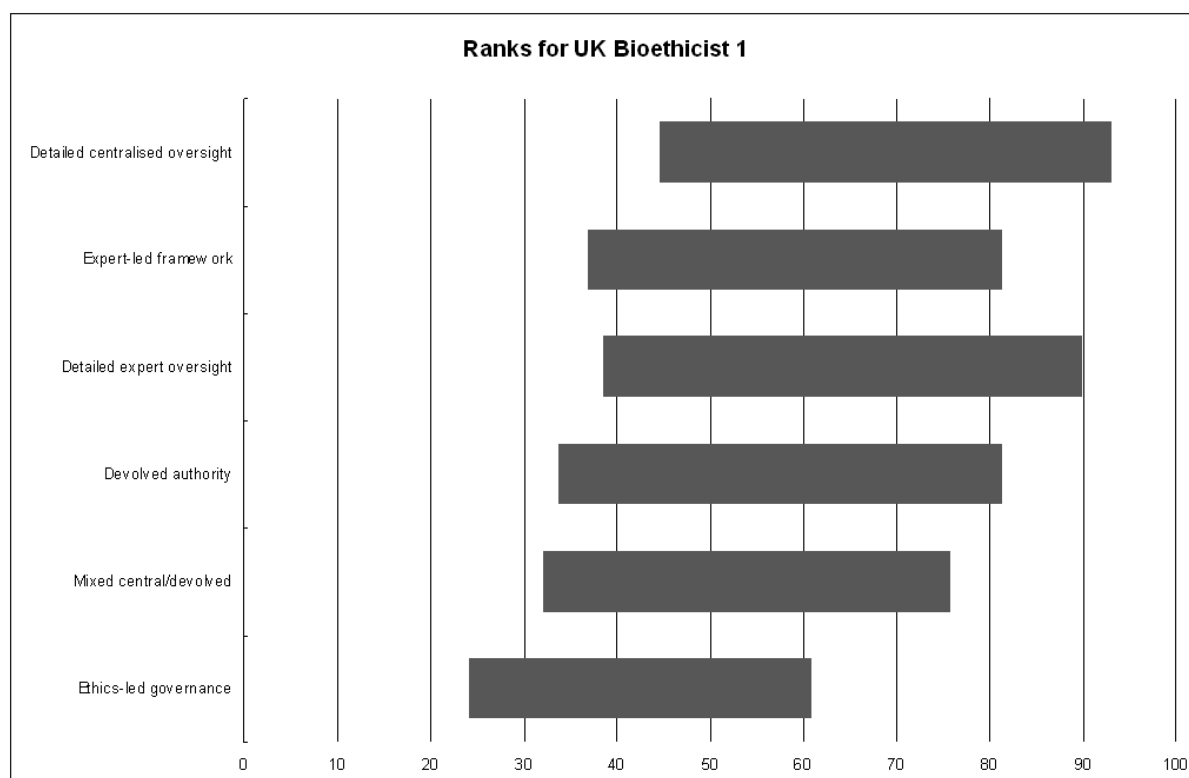


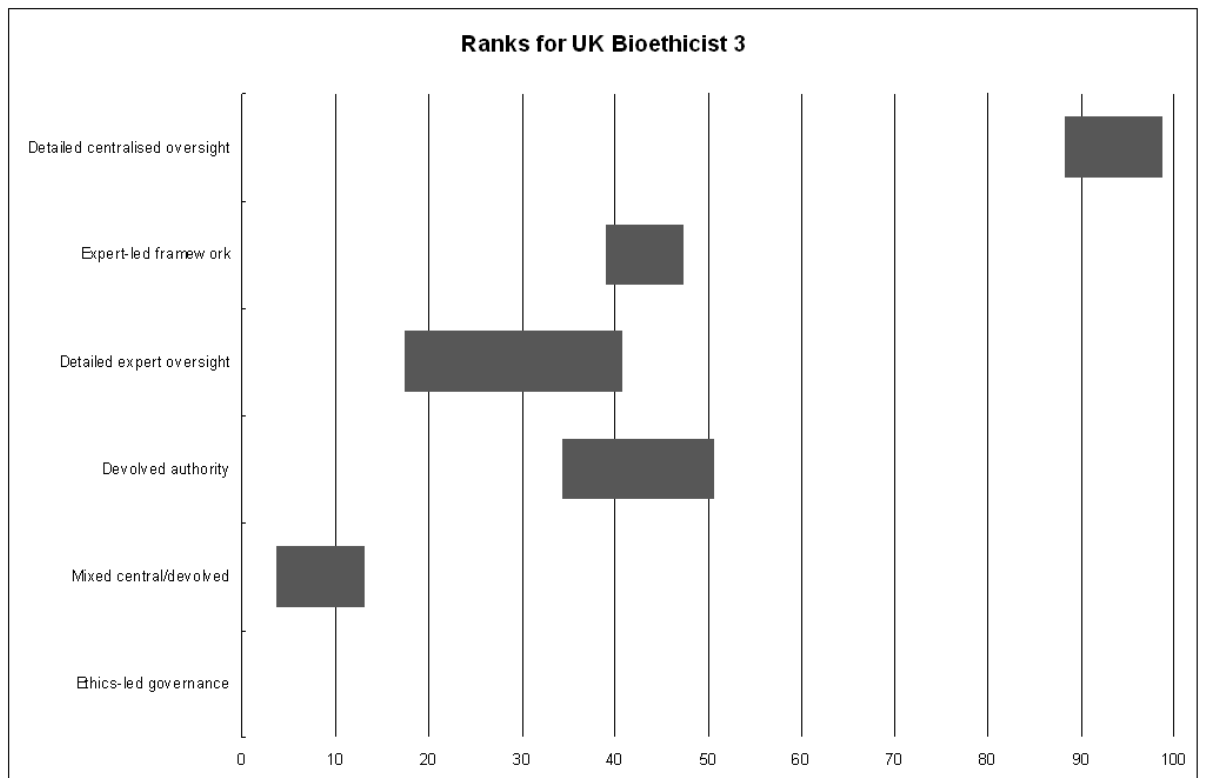
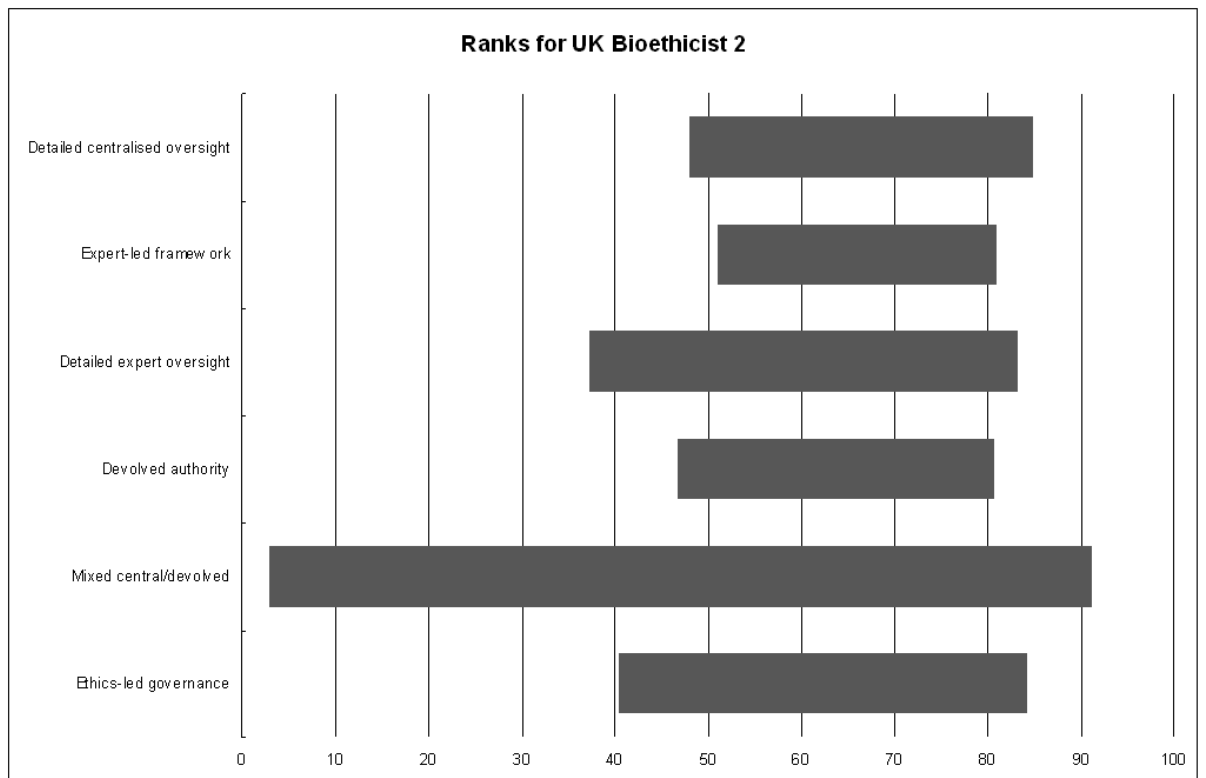


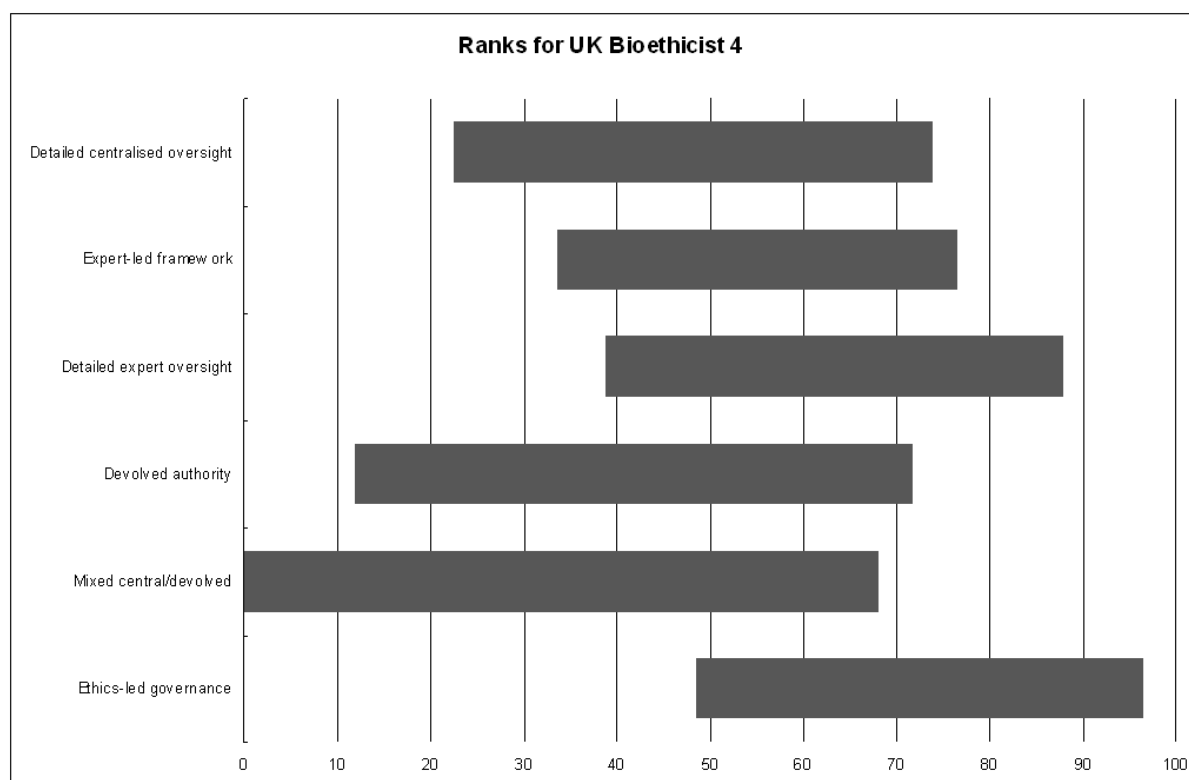




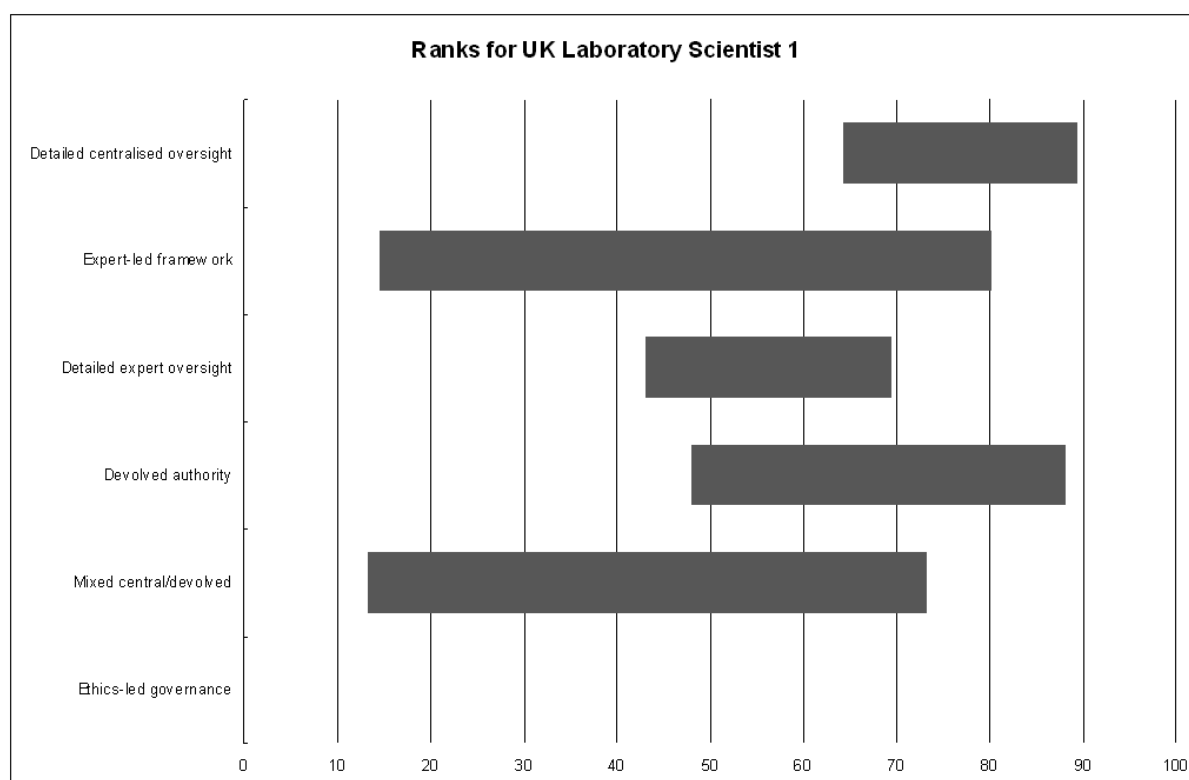
Ranks for UK Bioethicists

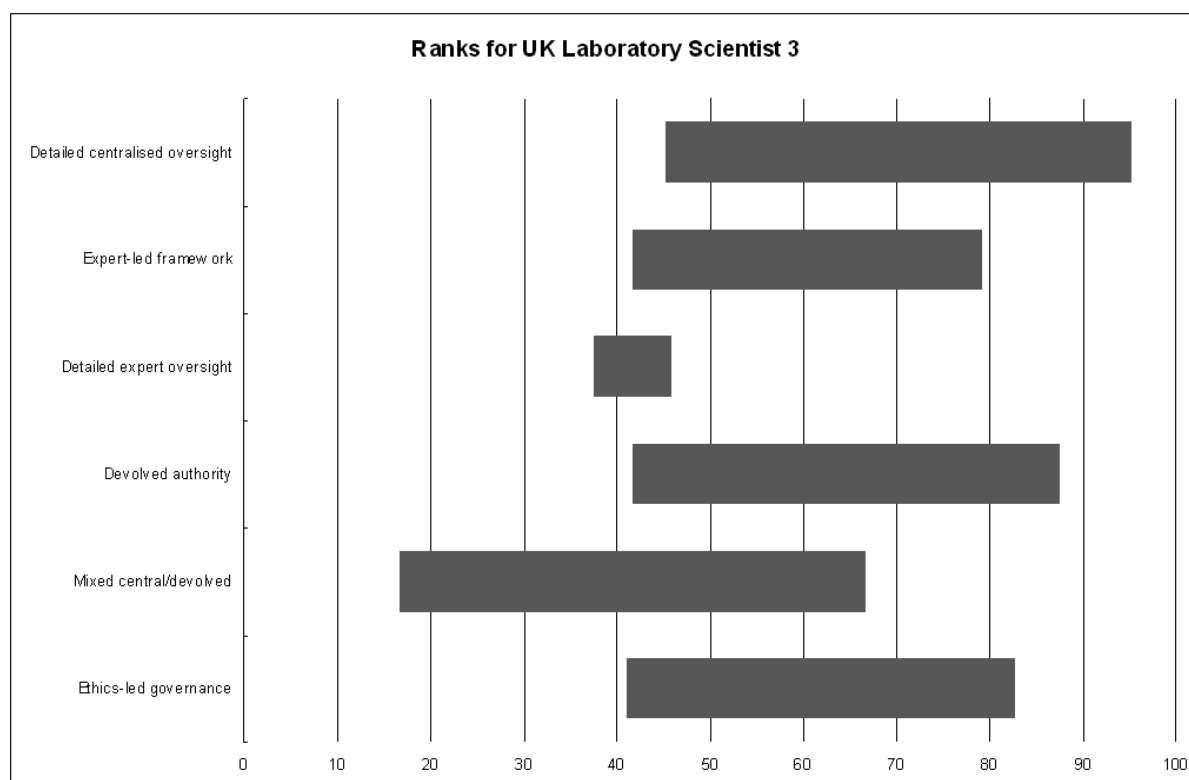
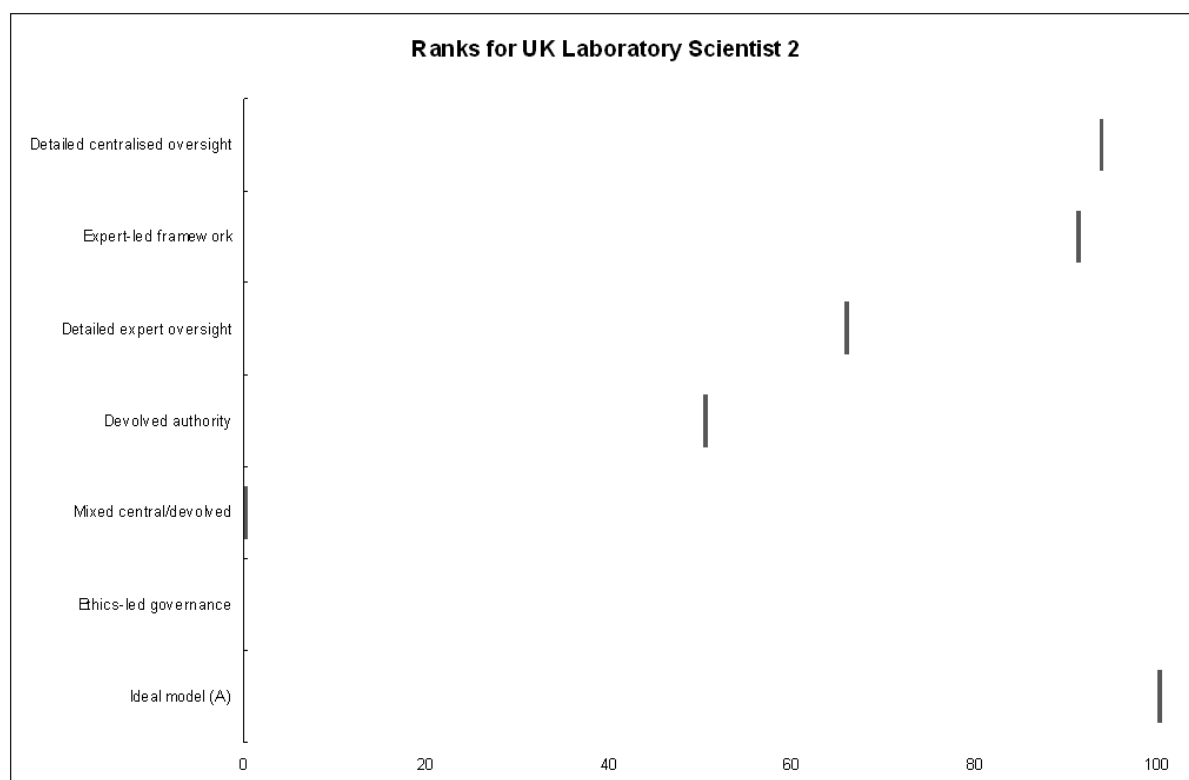


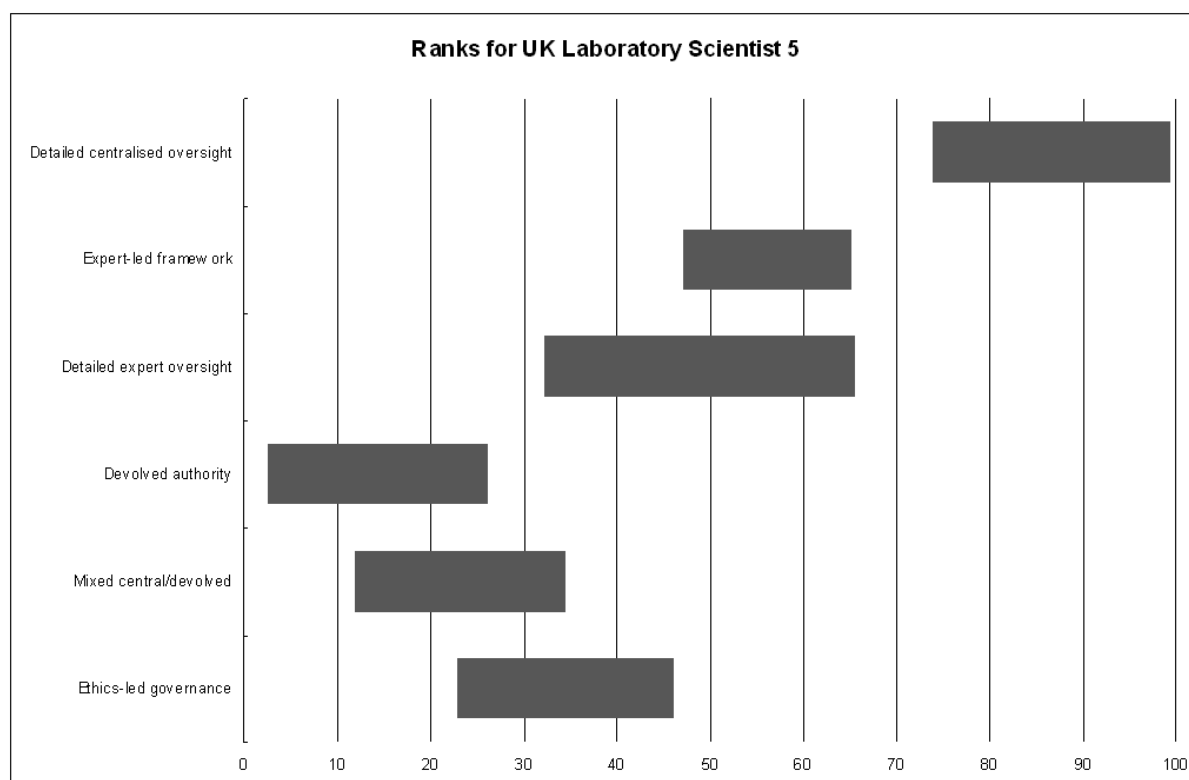
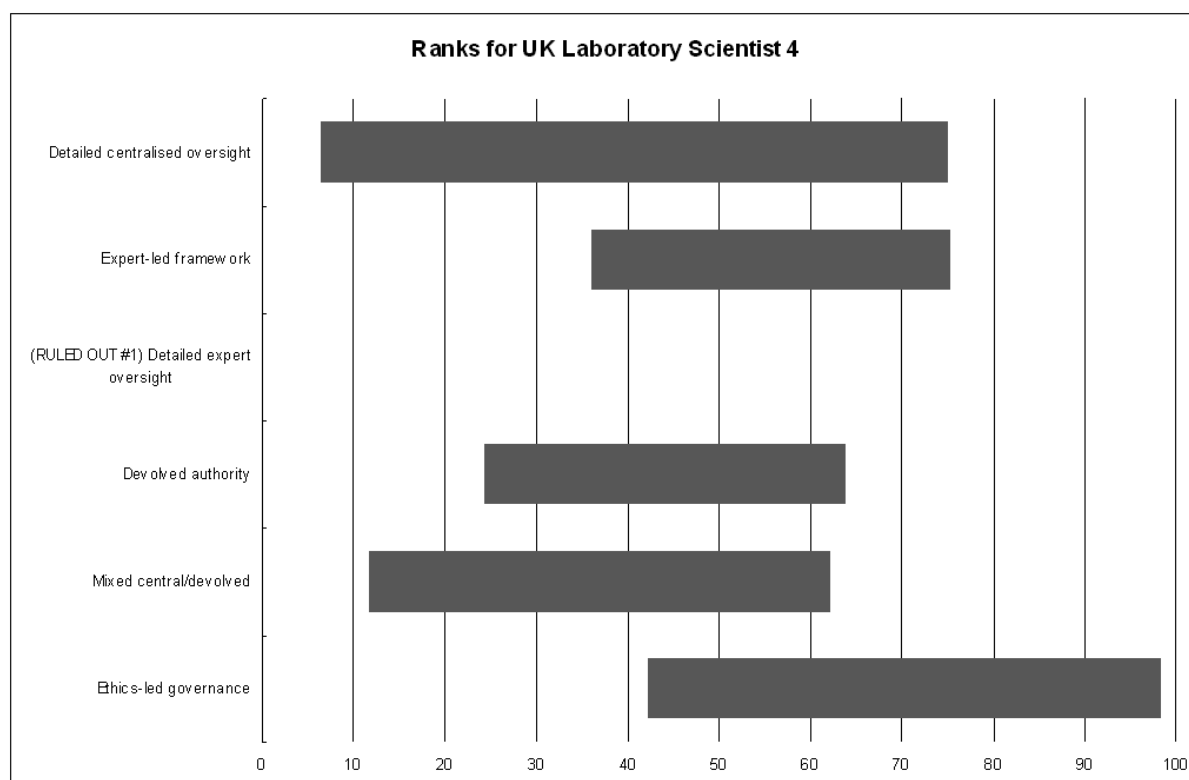


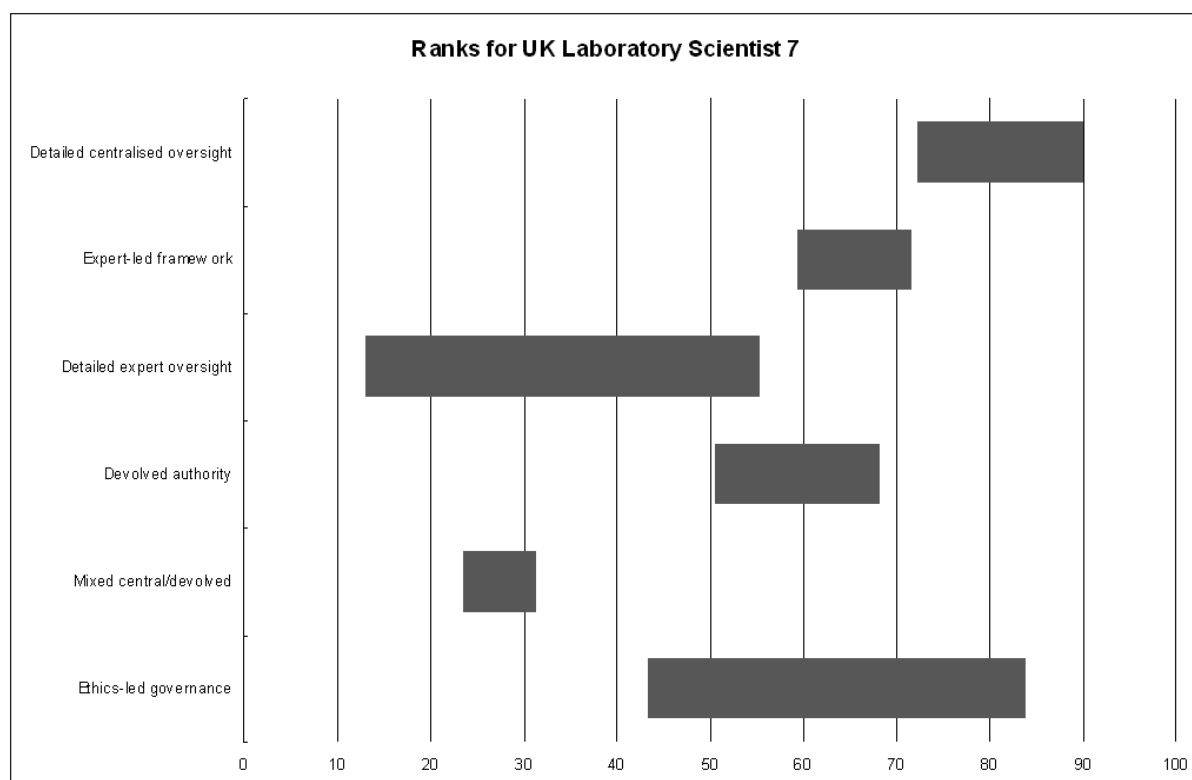
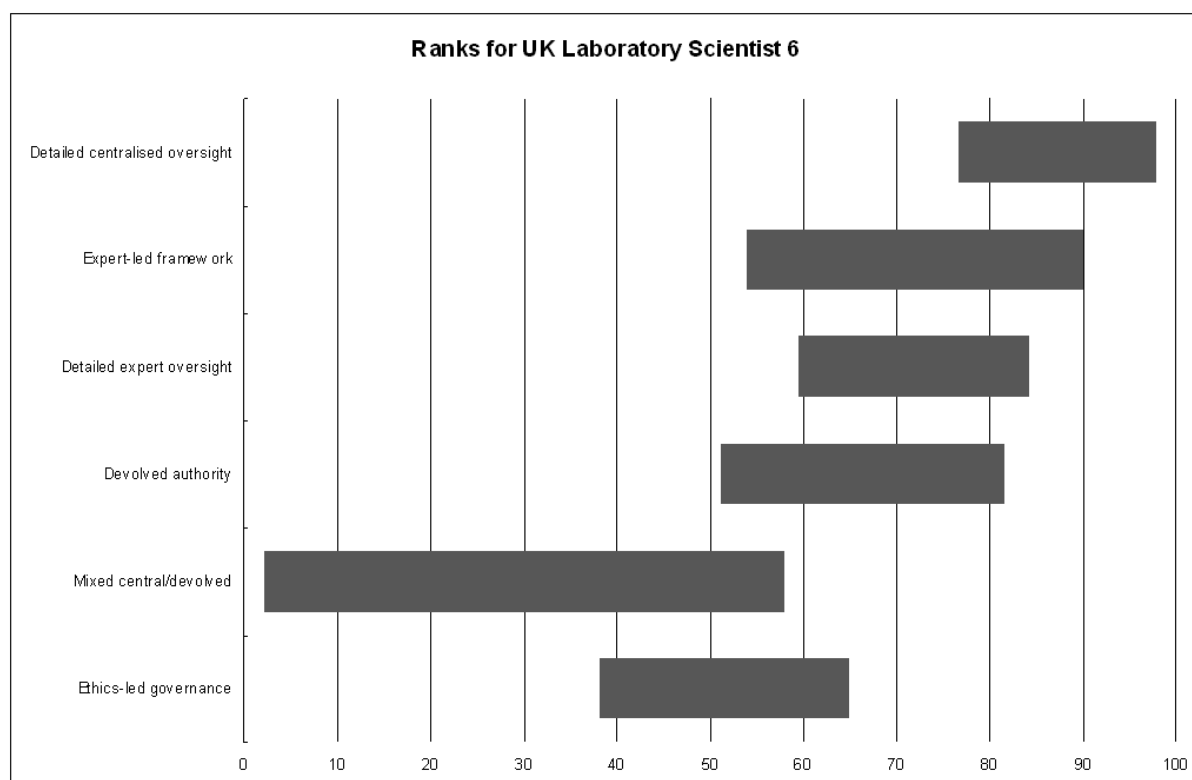


Ranks for UK Laboratory Scientists

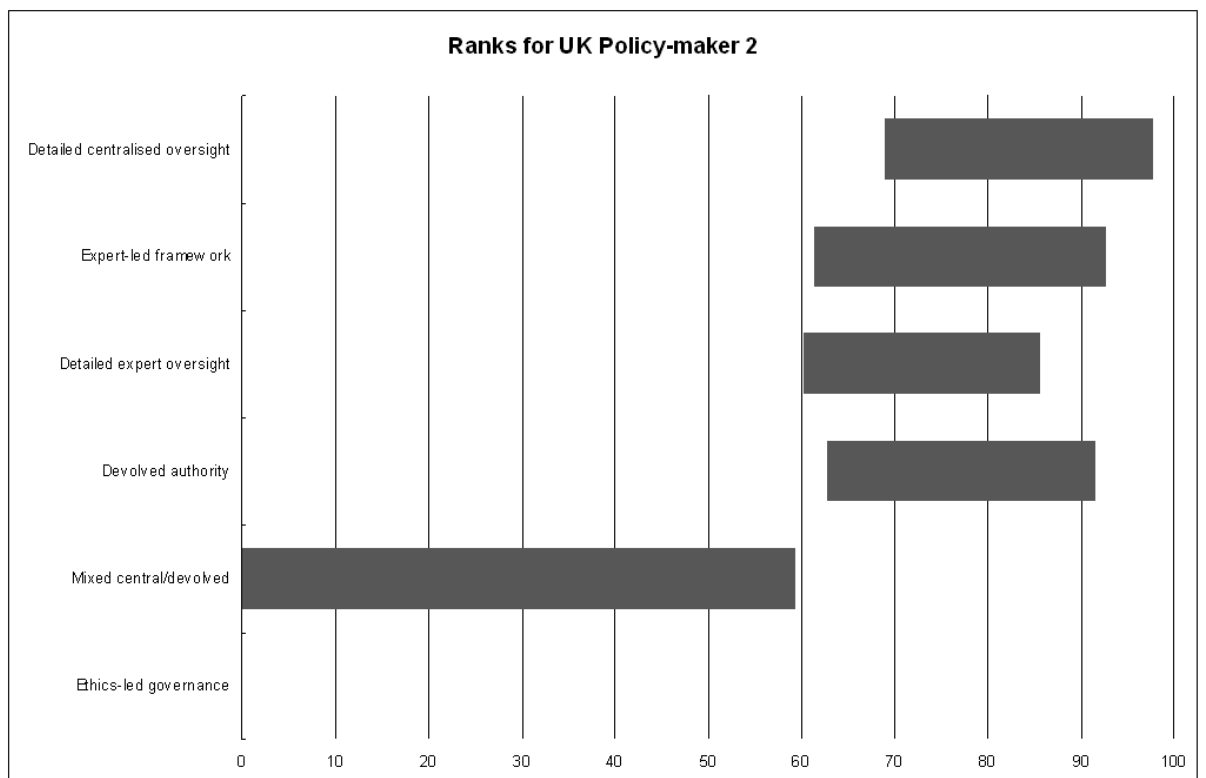
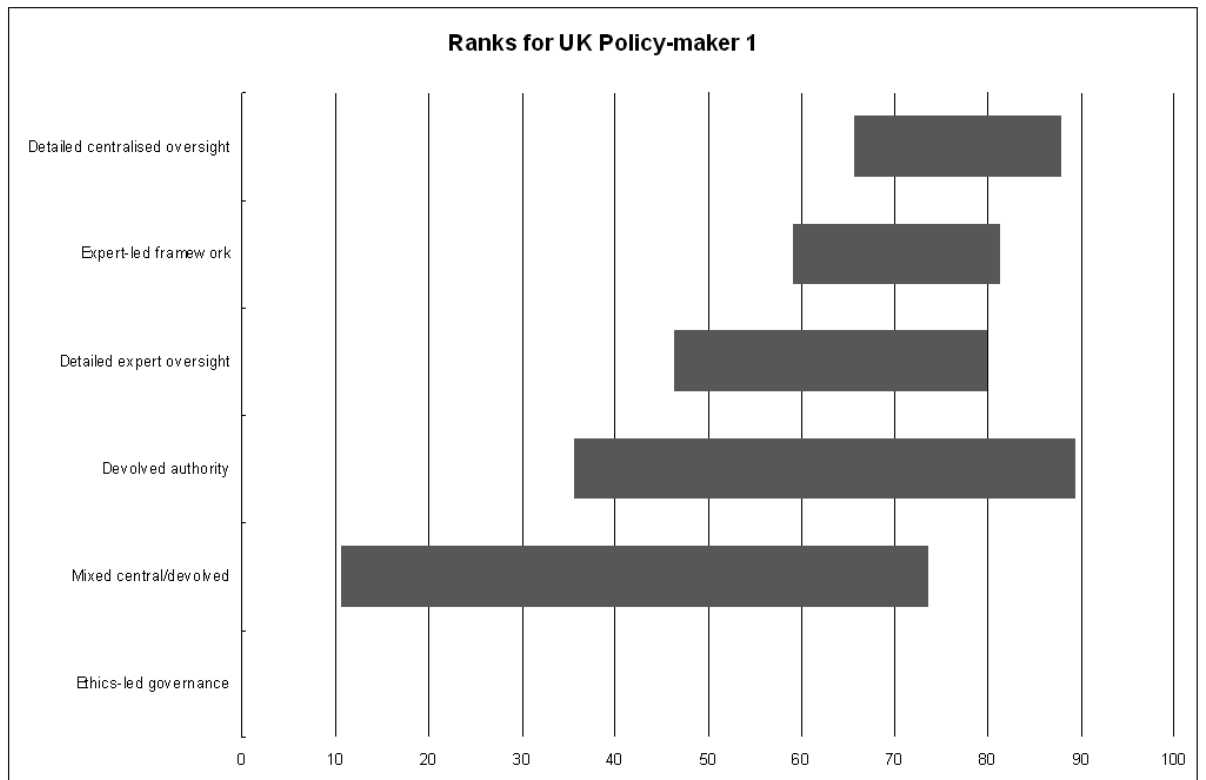


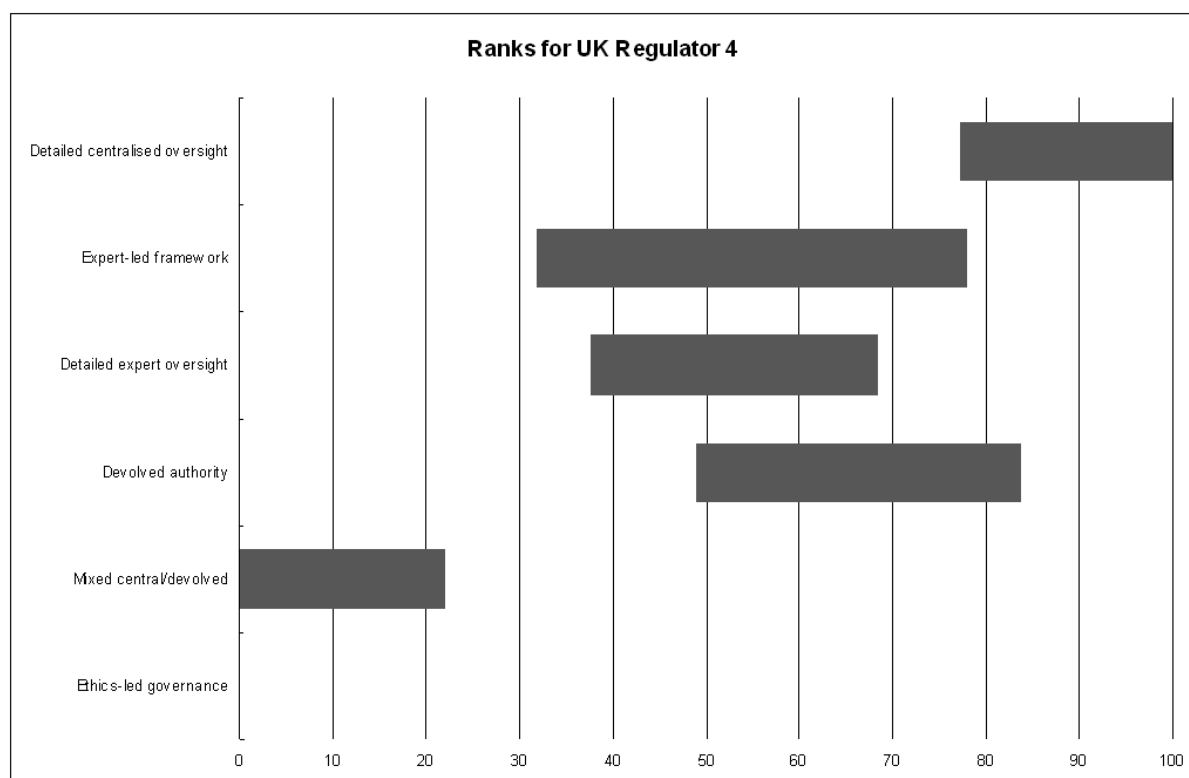
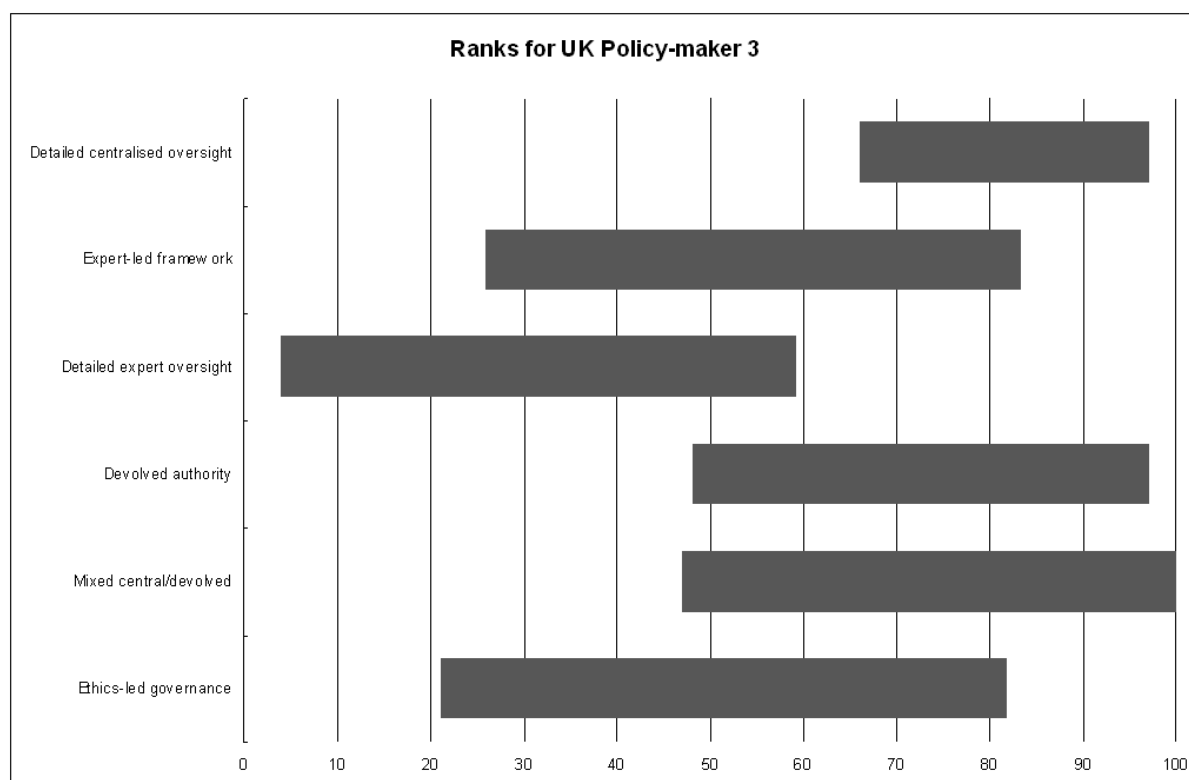




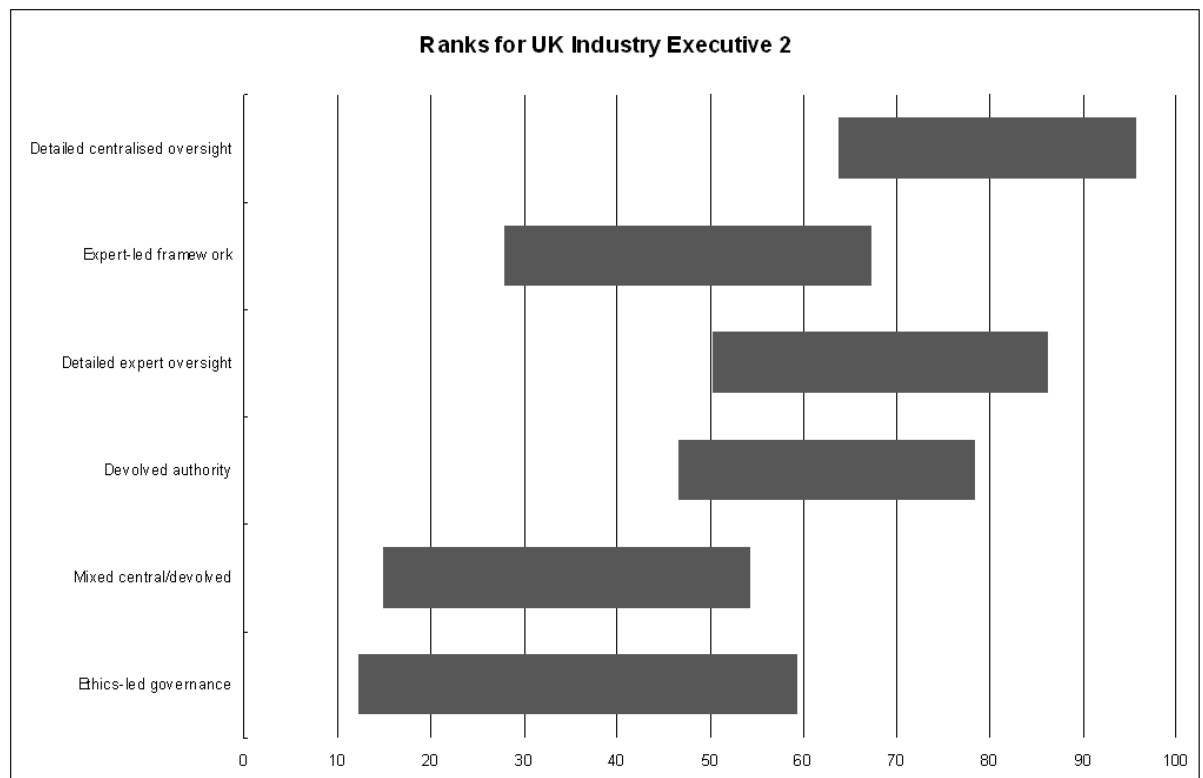
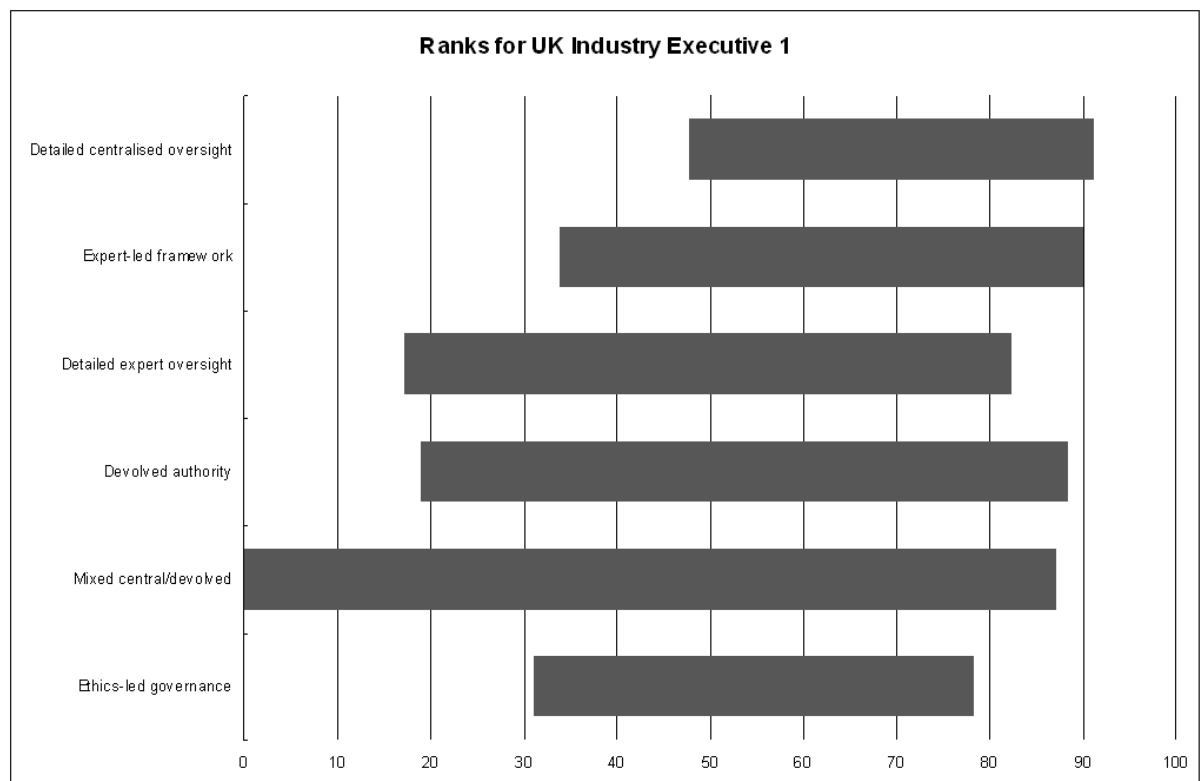


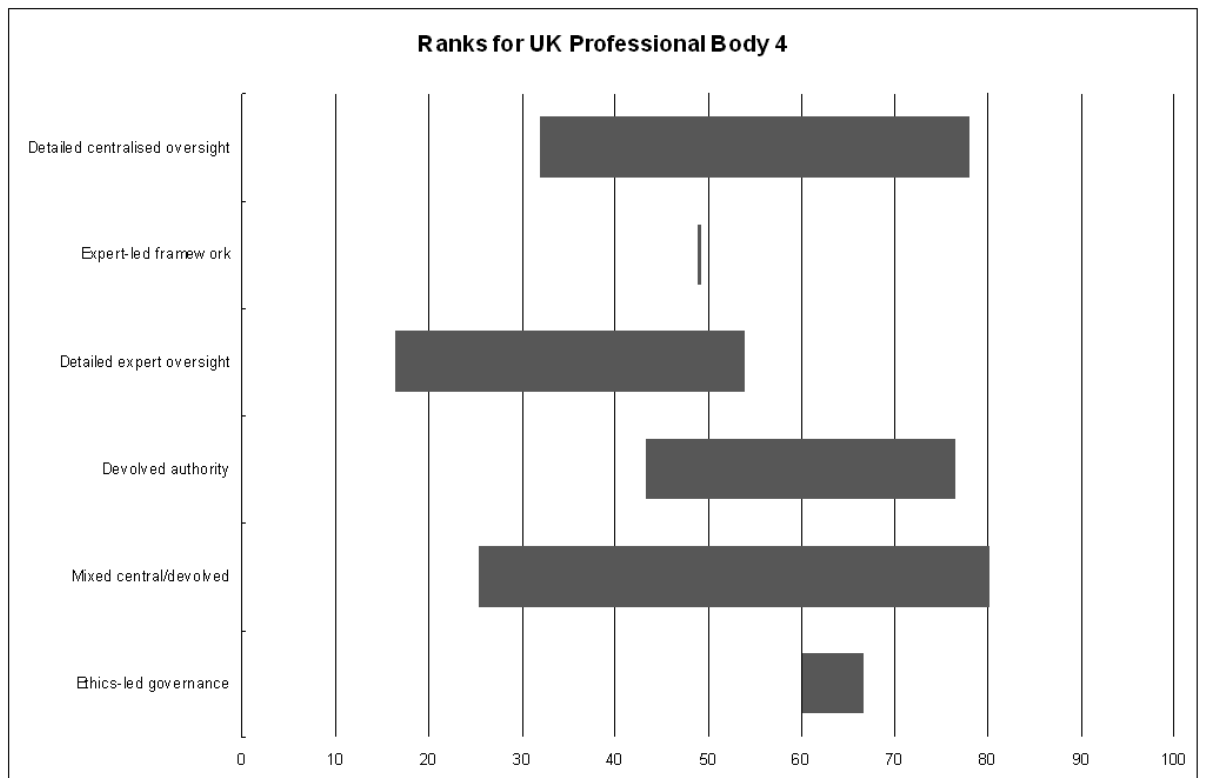
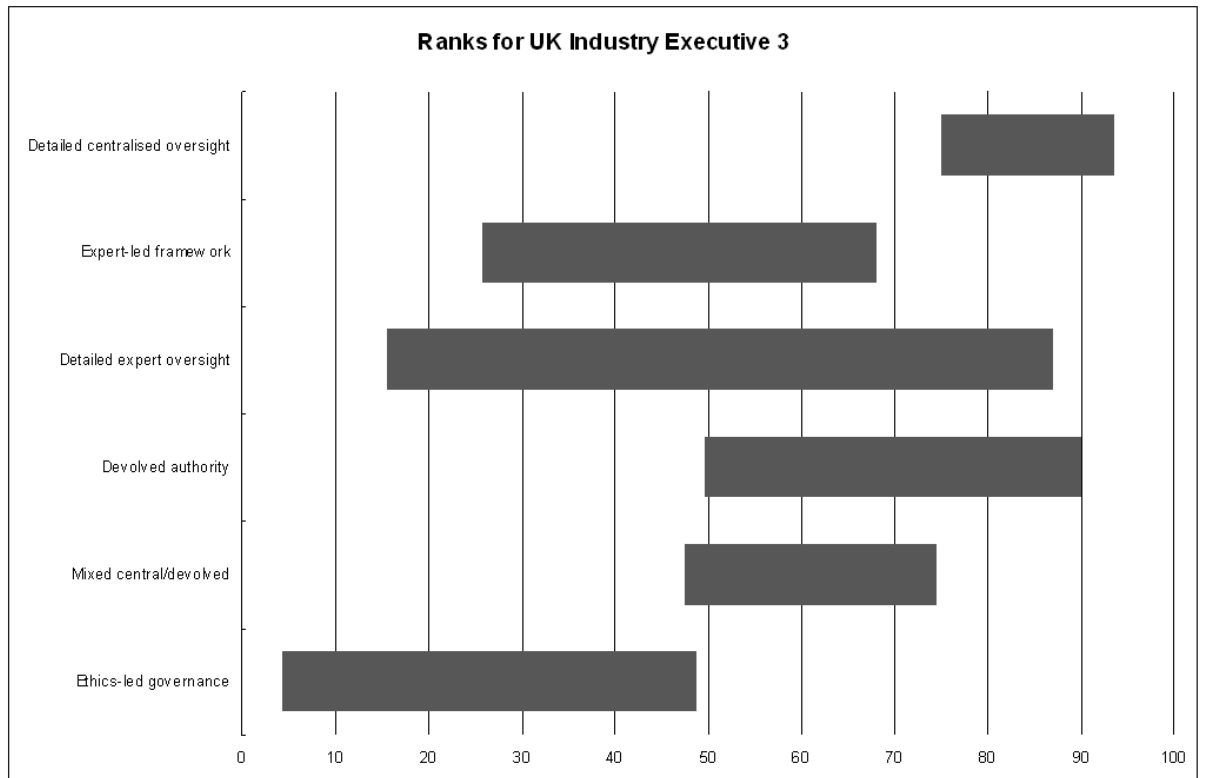
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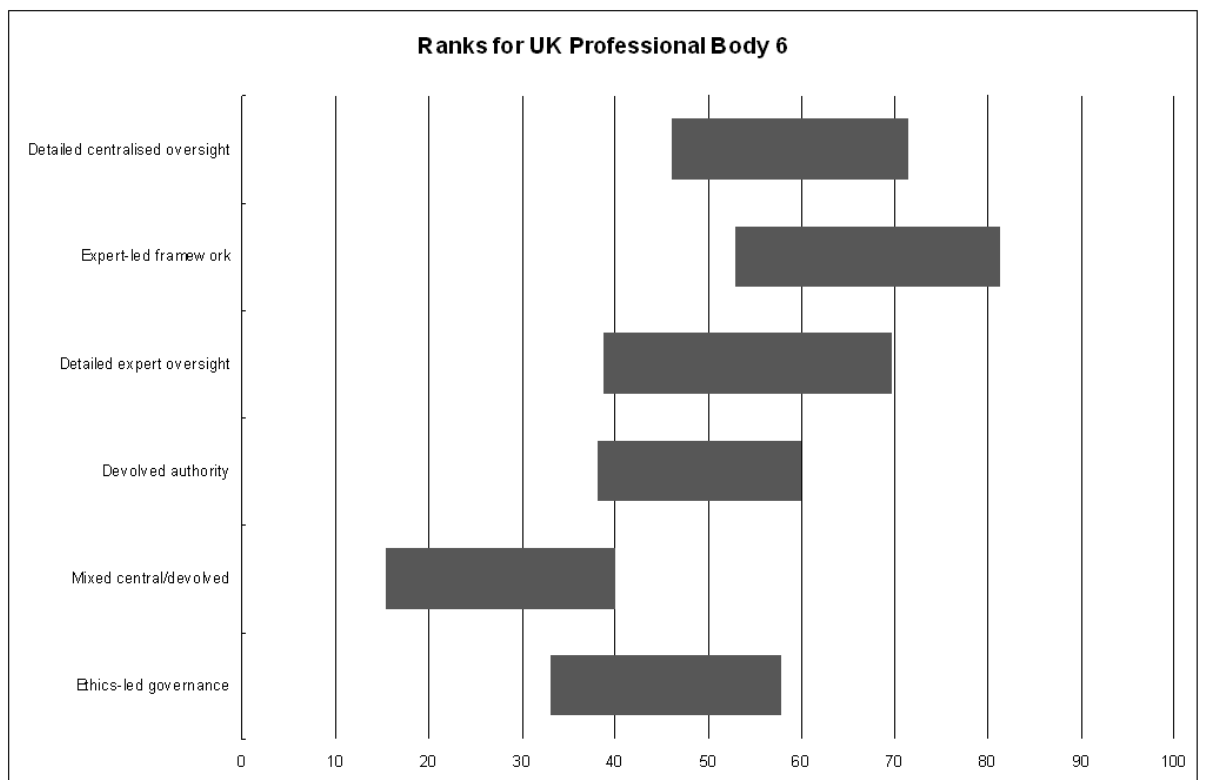
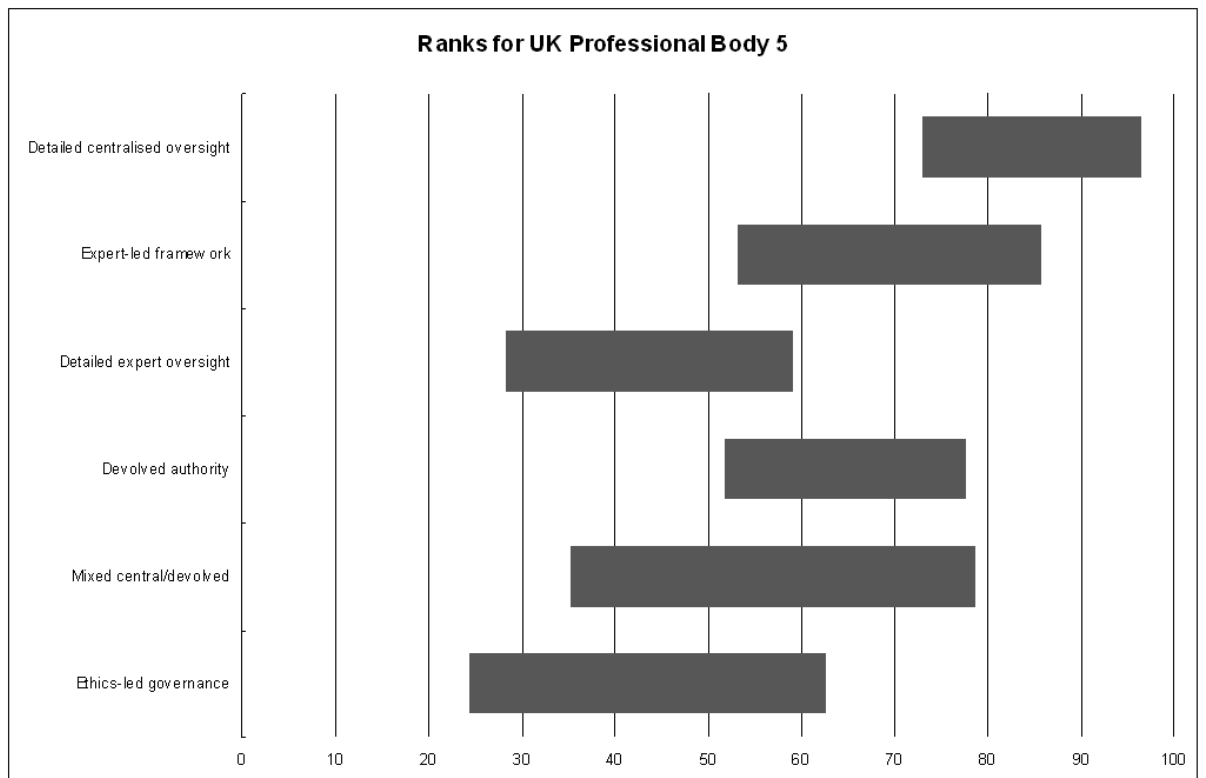




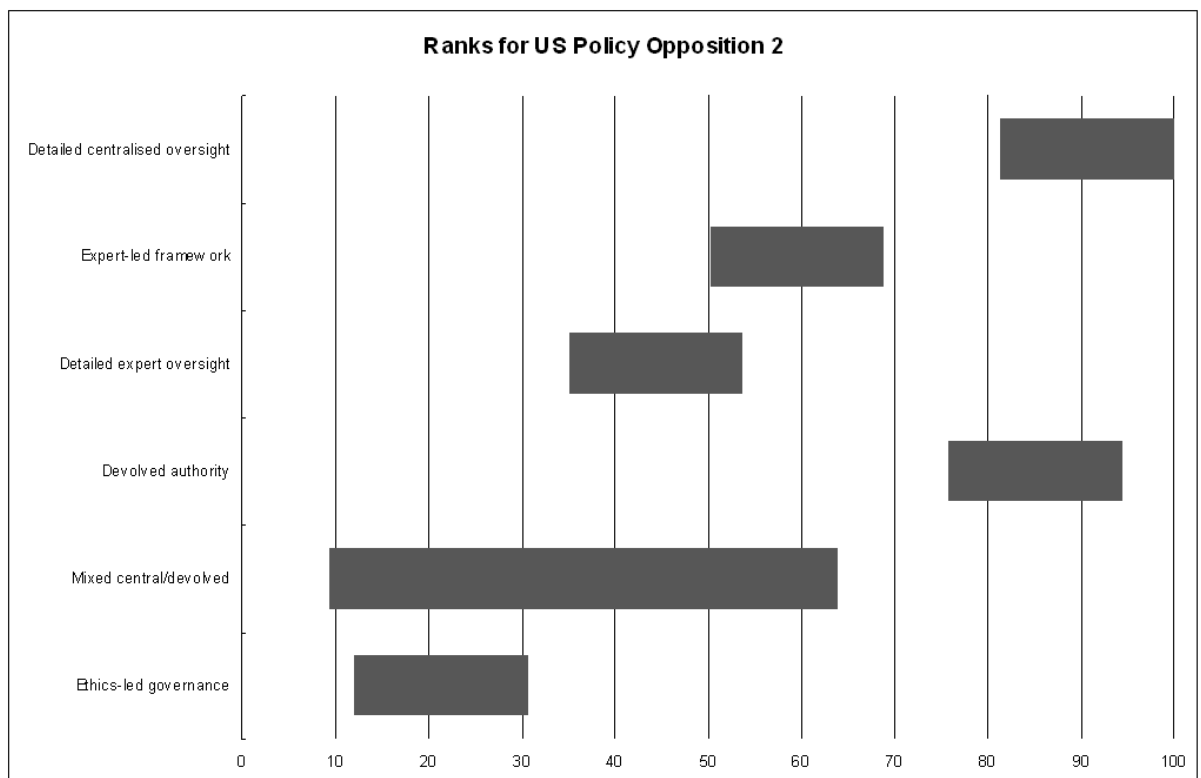
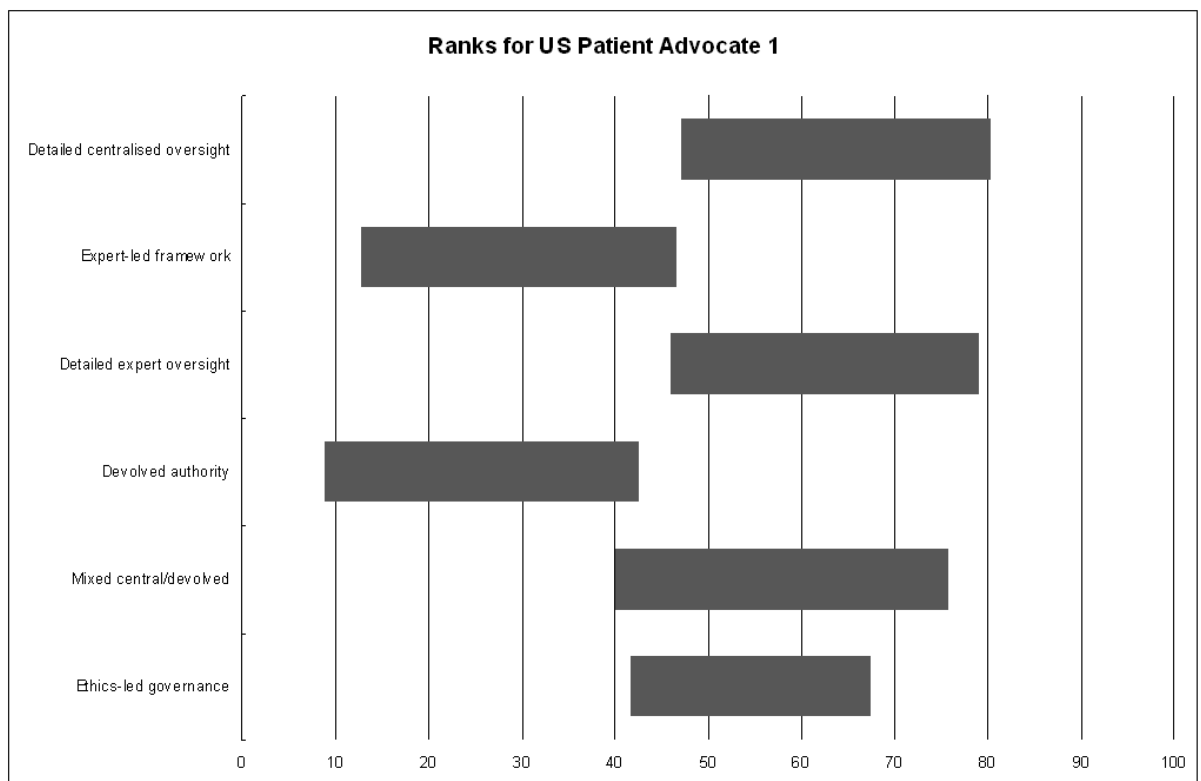
Ranks for UK Industry and Professional Body Executives

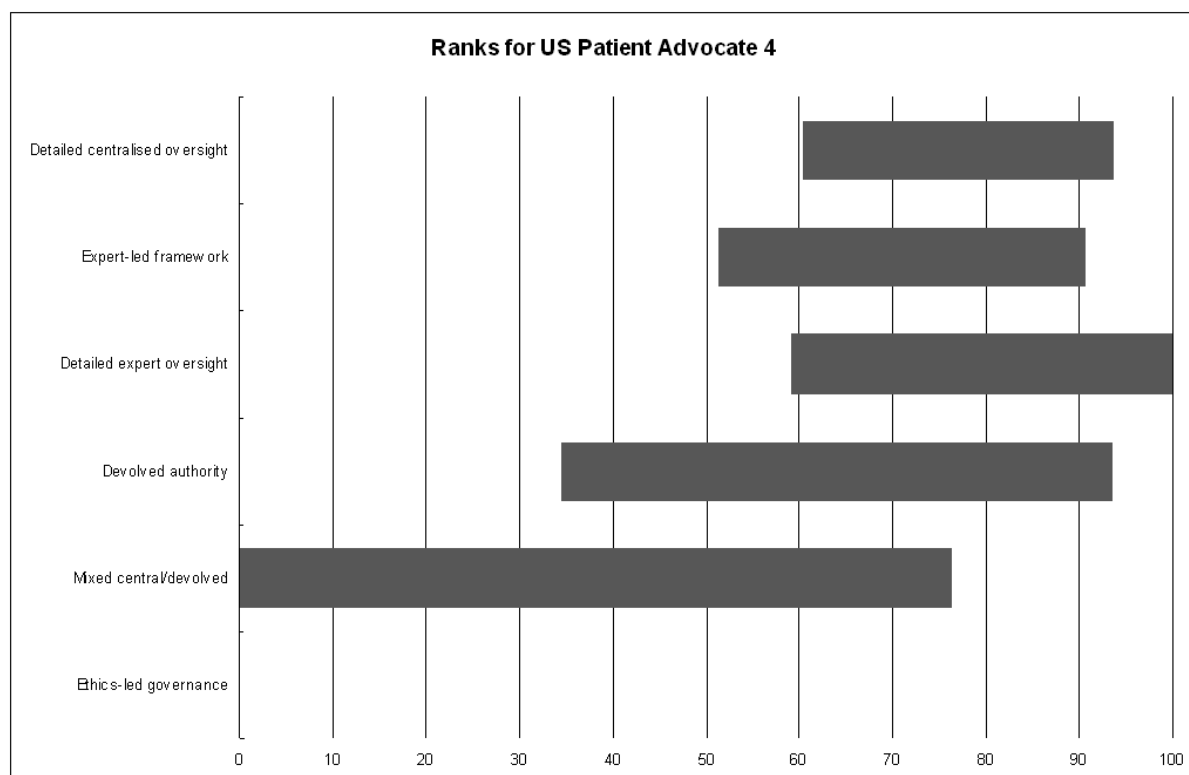
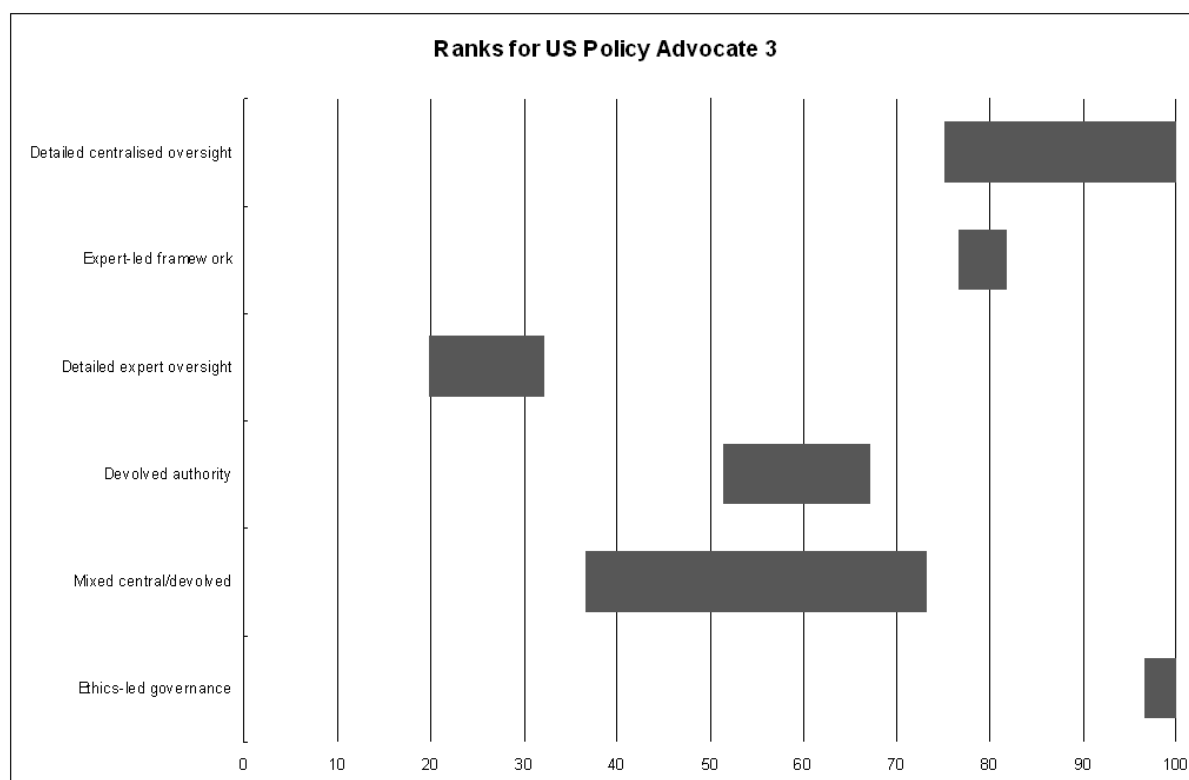


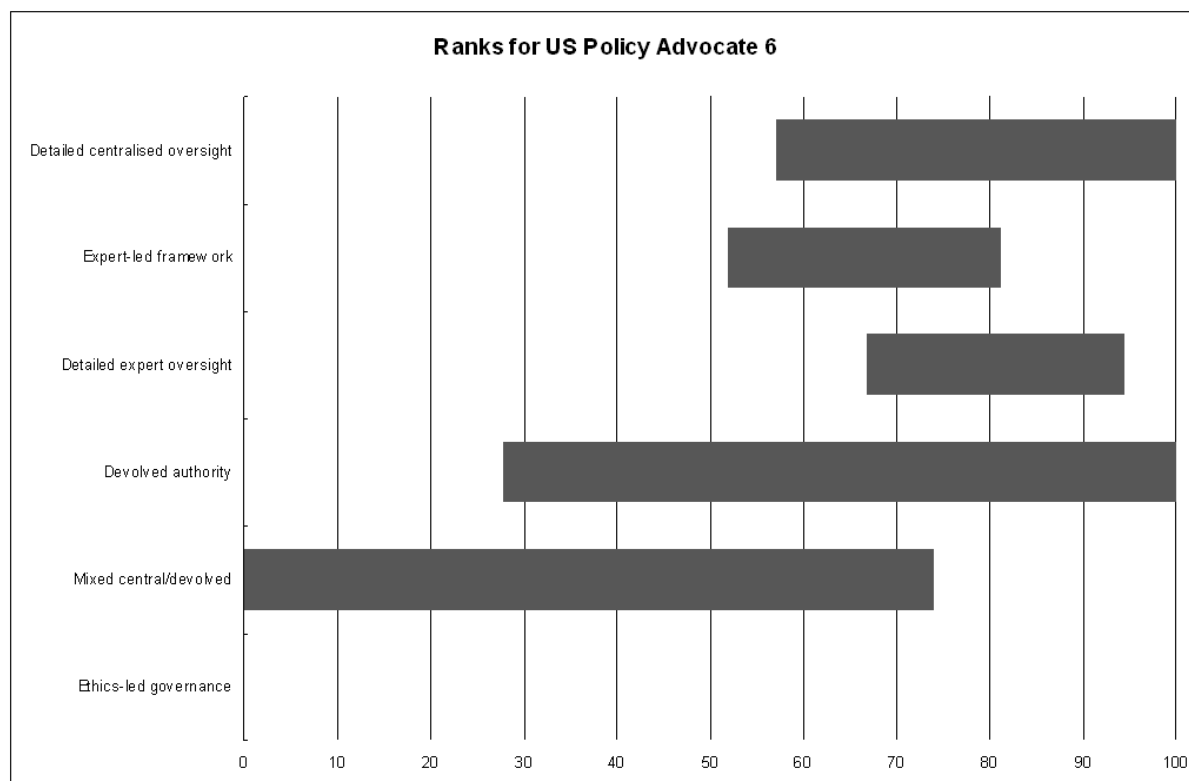
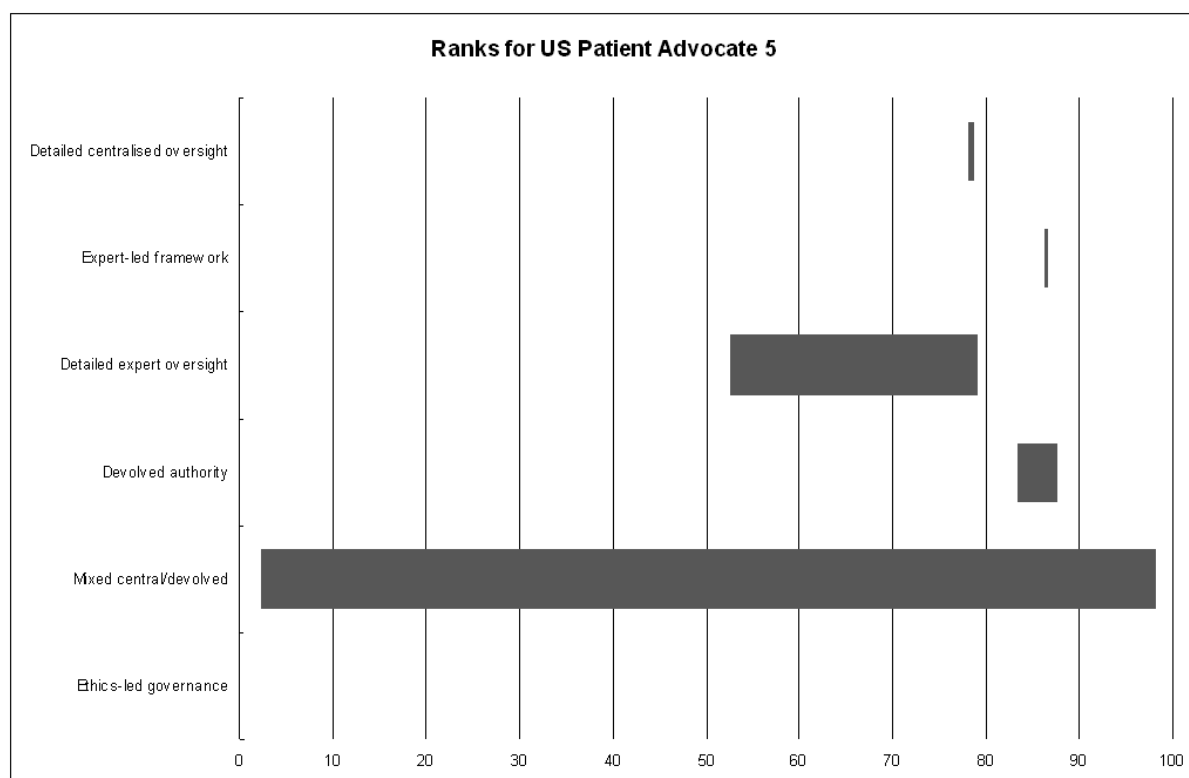




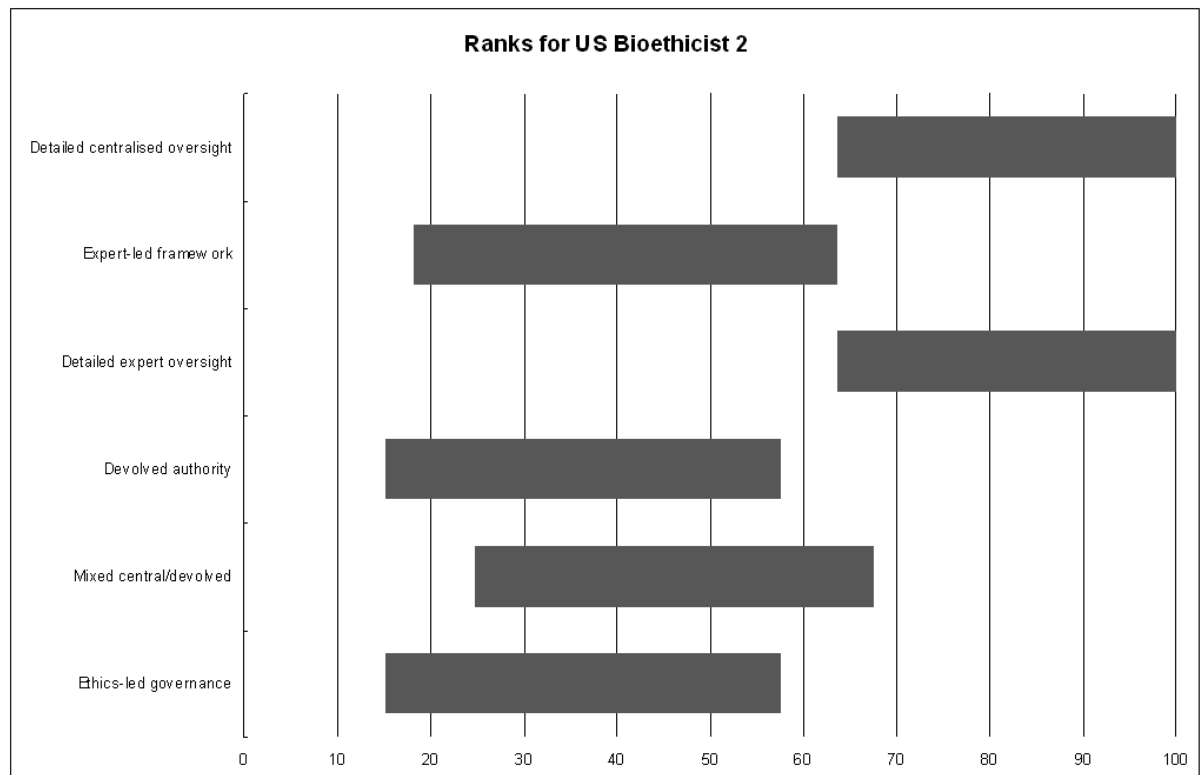
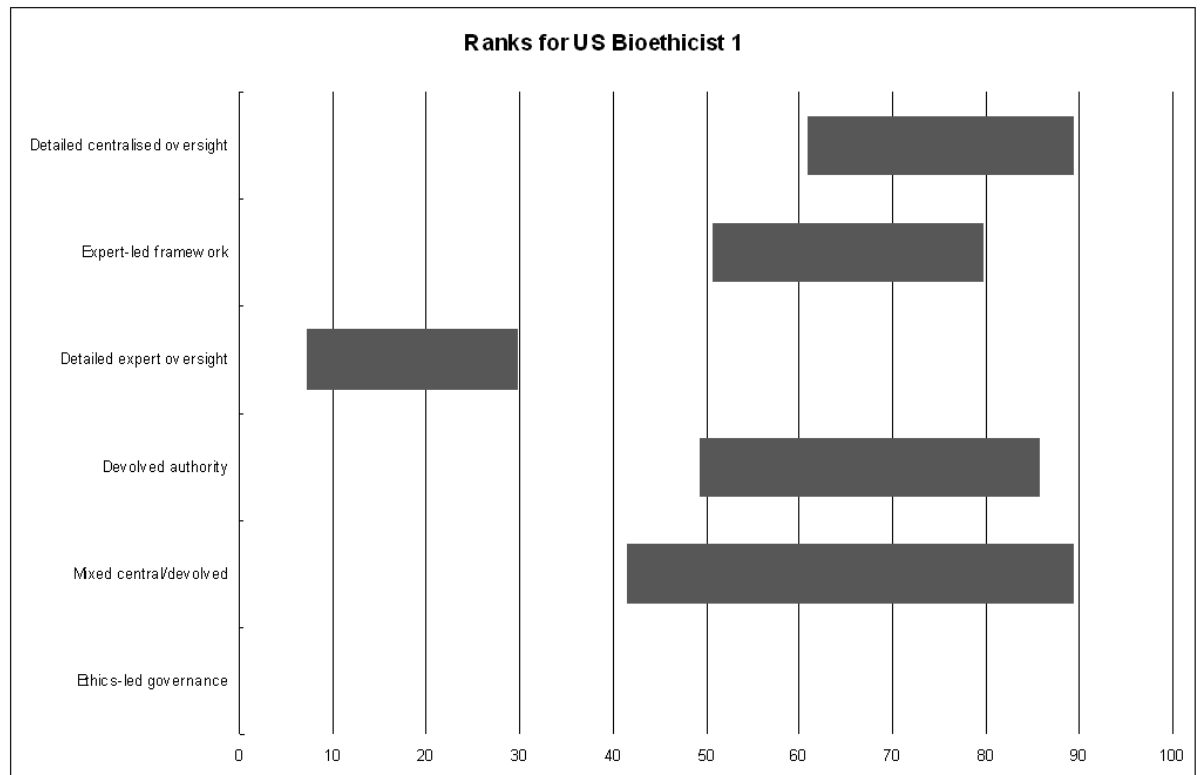
Ranks for US Patient and Policy Advocates

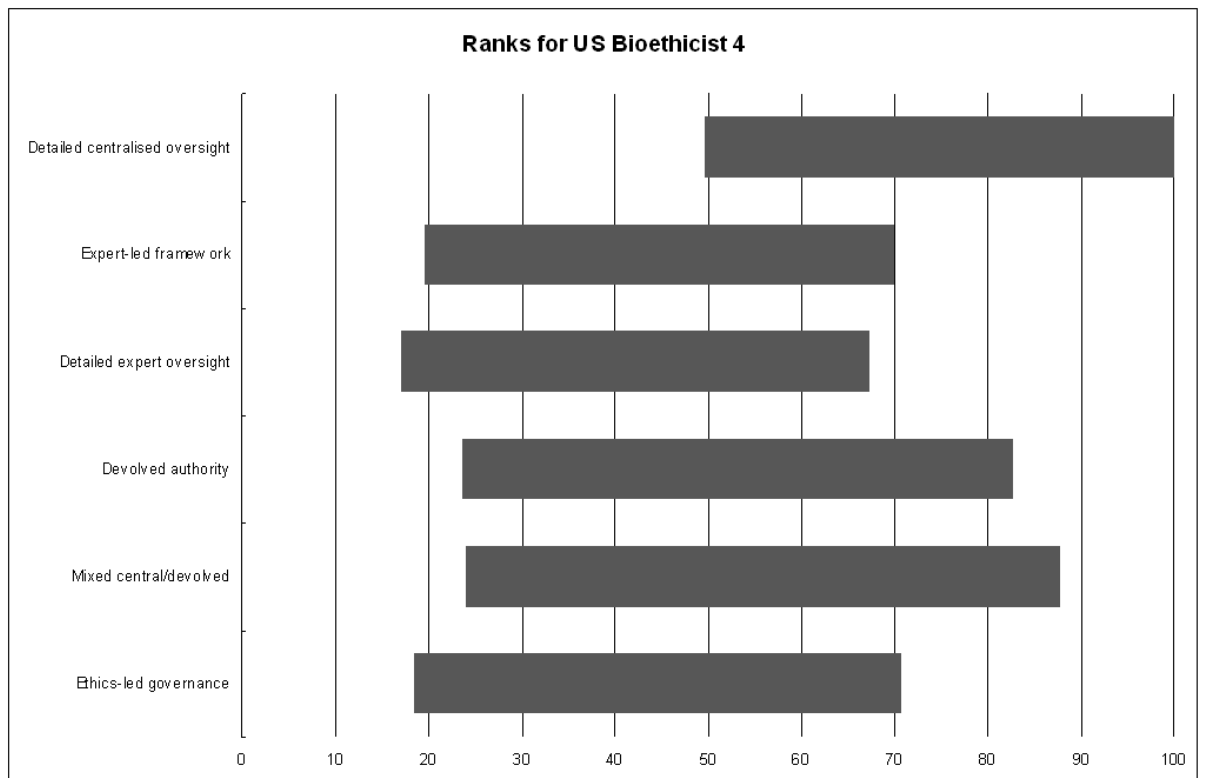
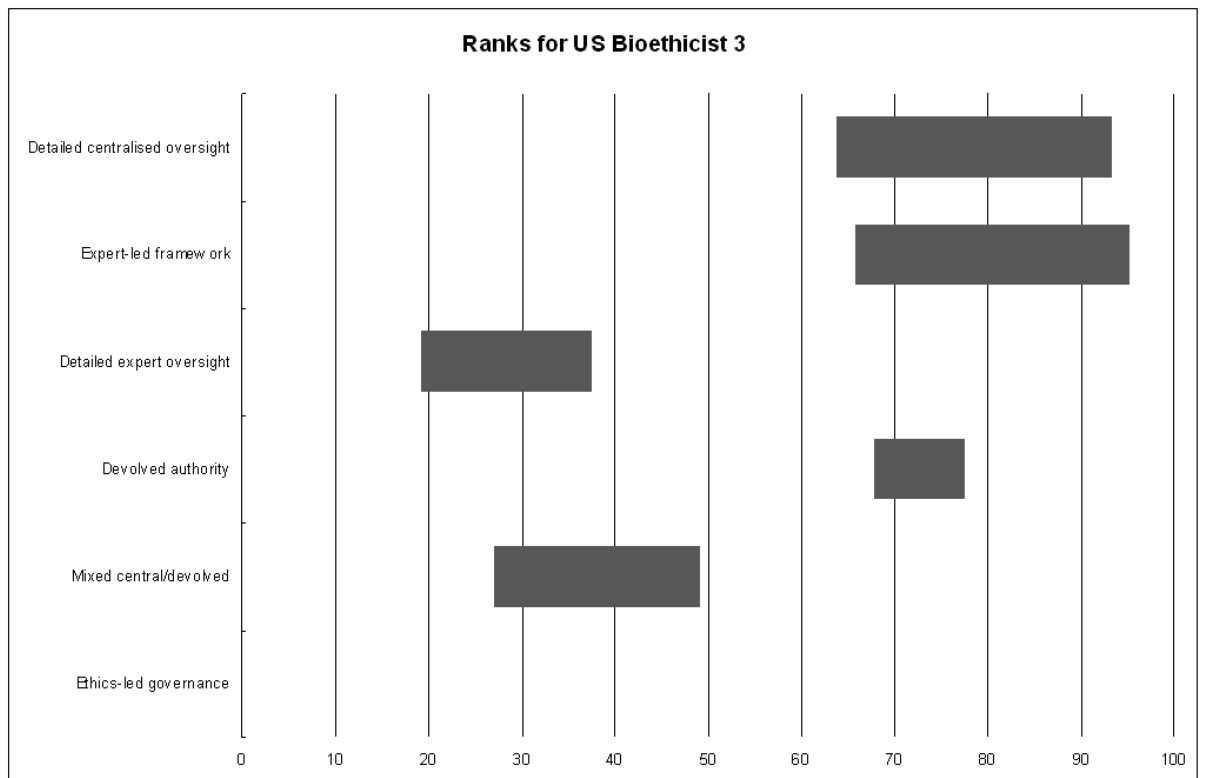


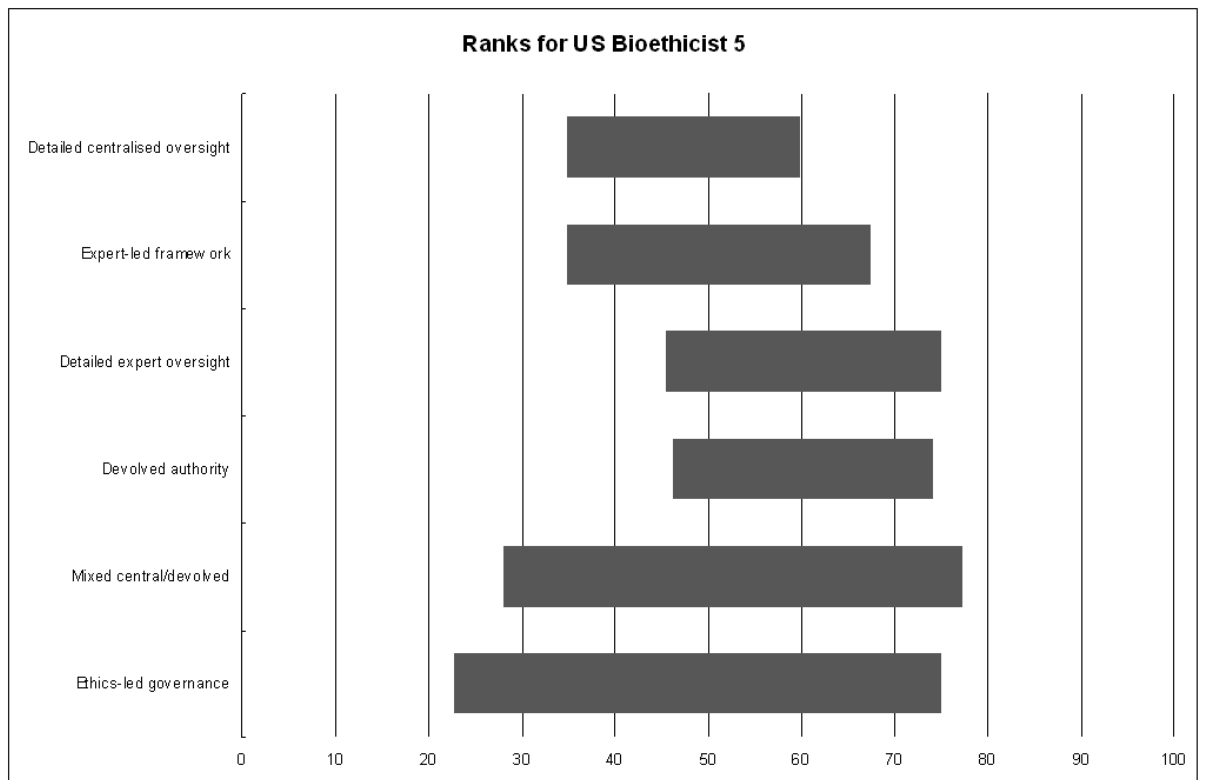




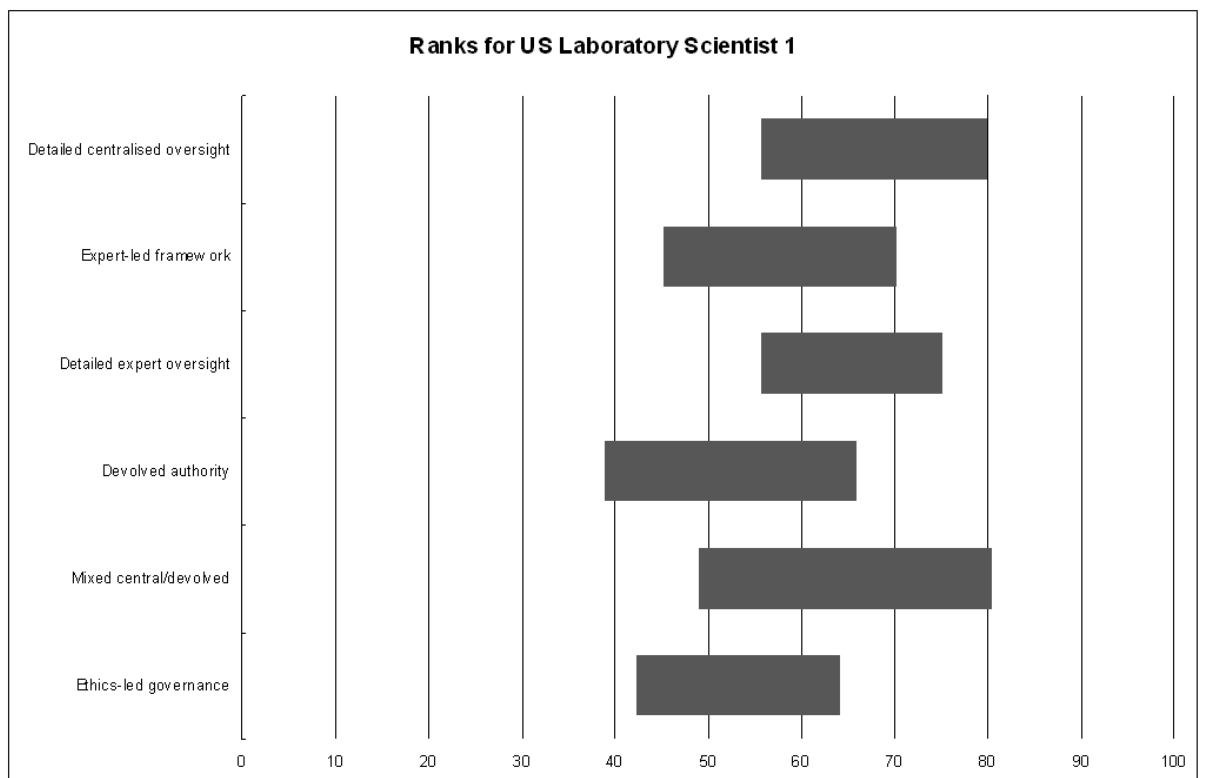
Ranks for US Bioethicists

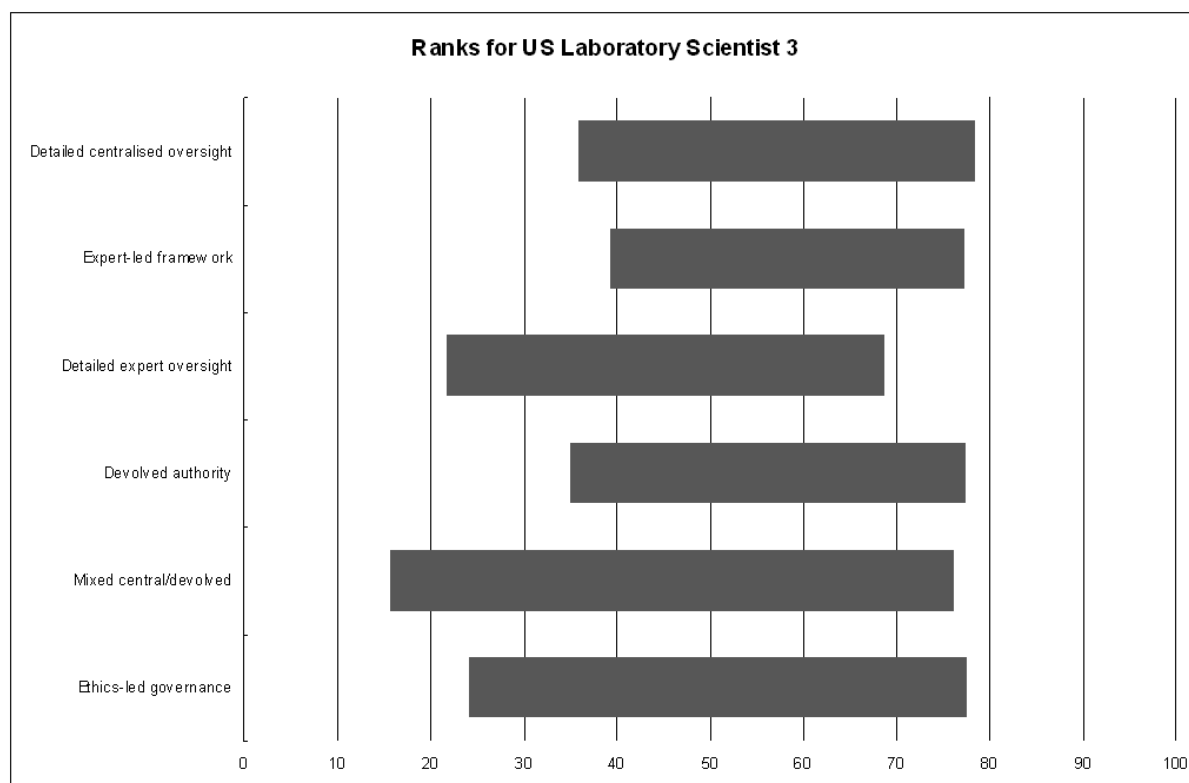
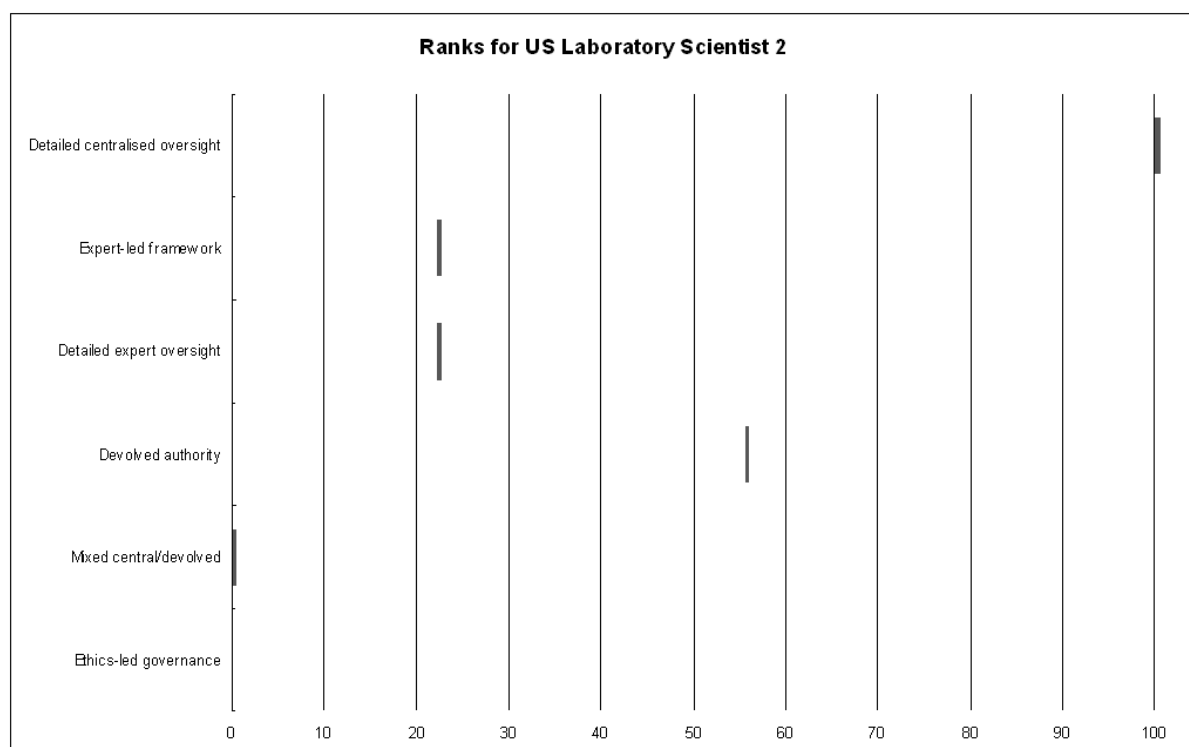


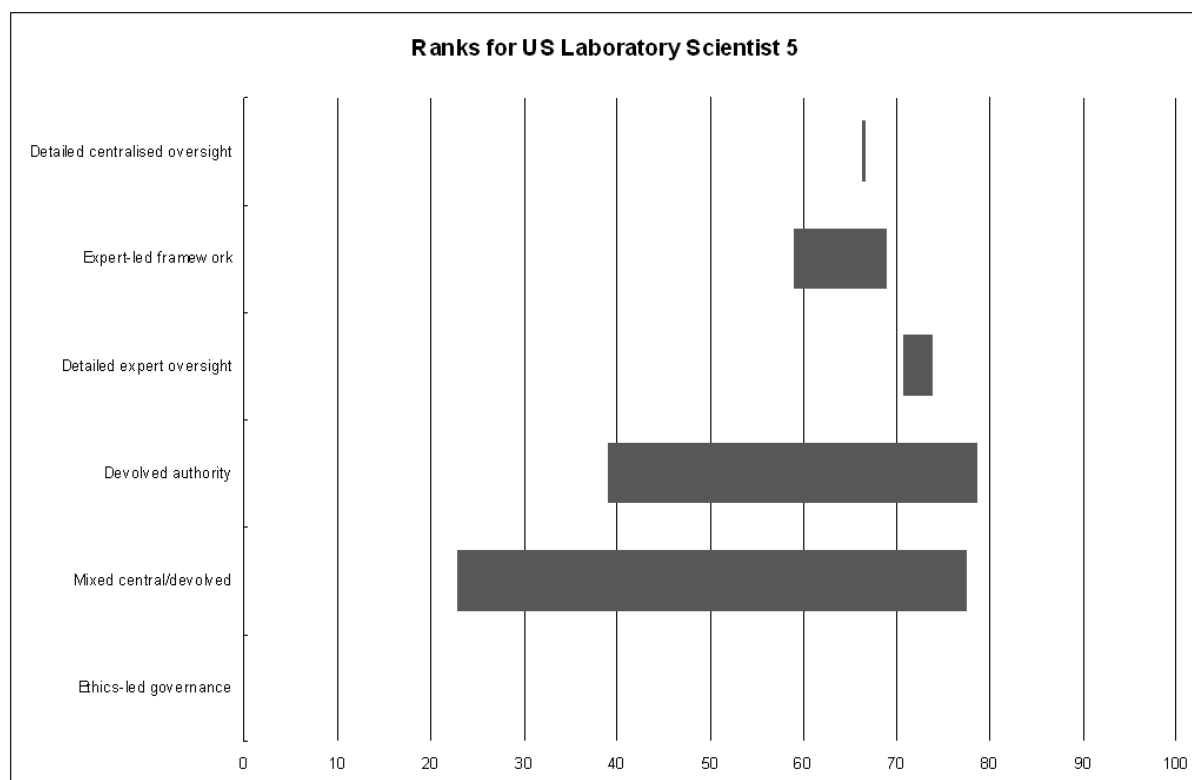
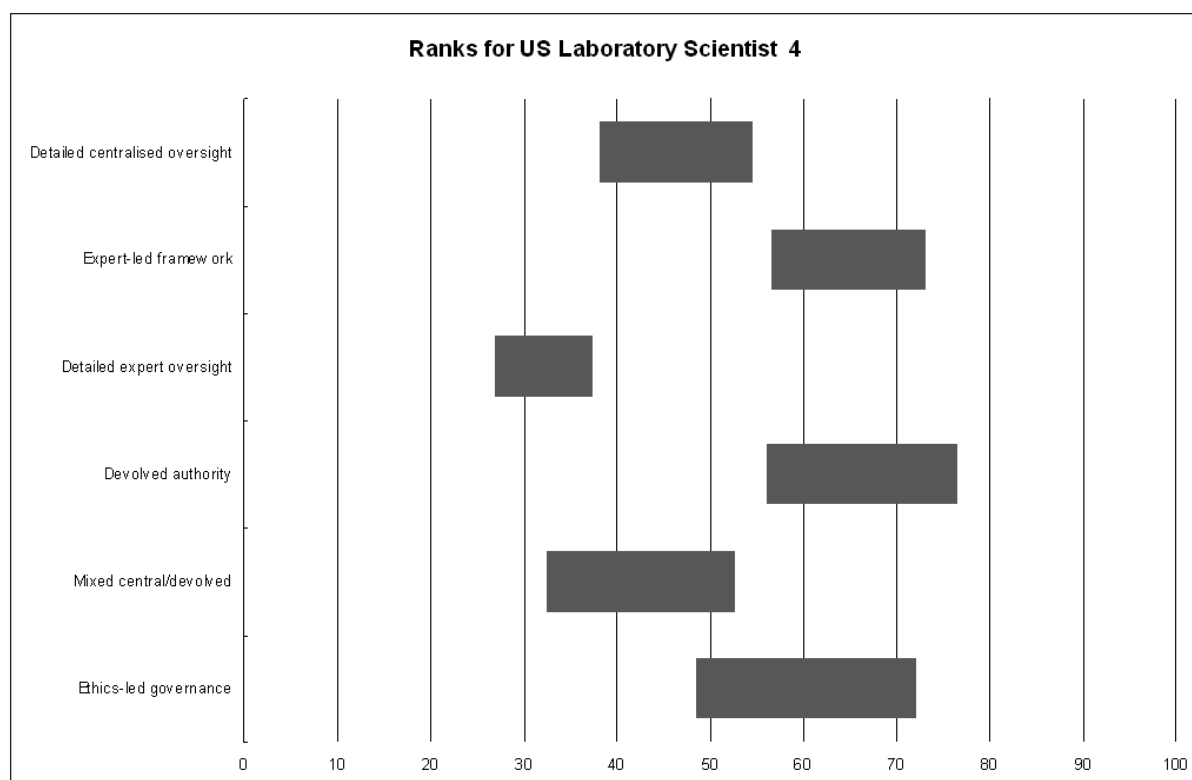




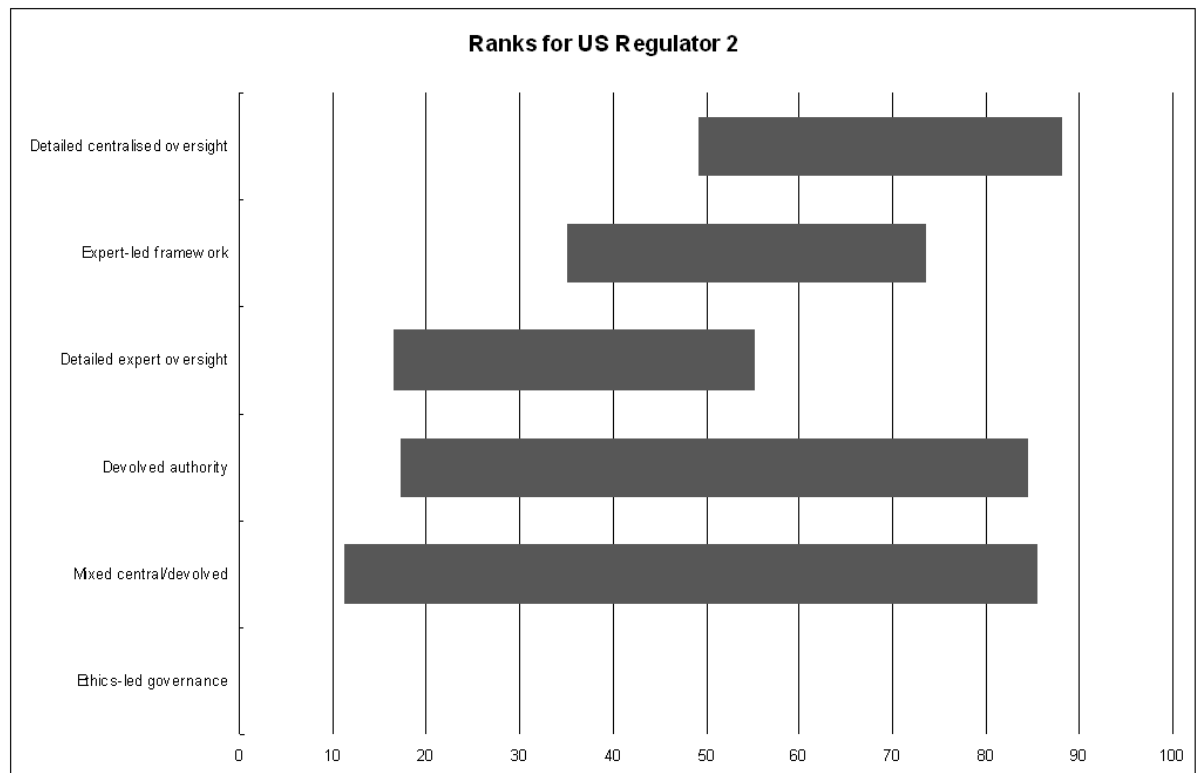
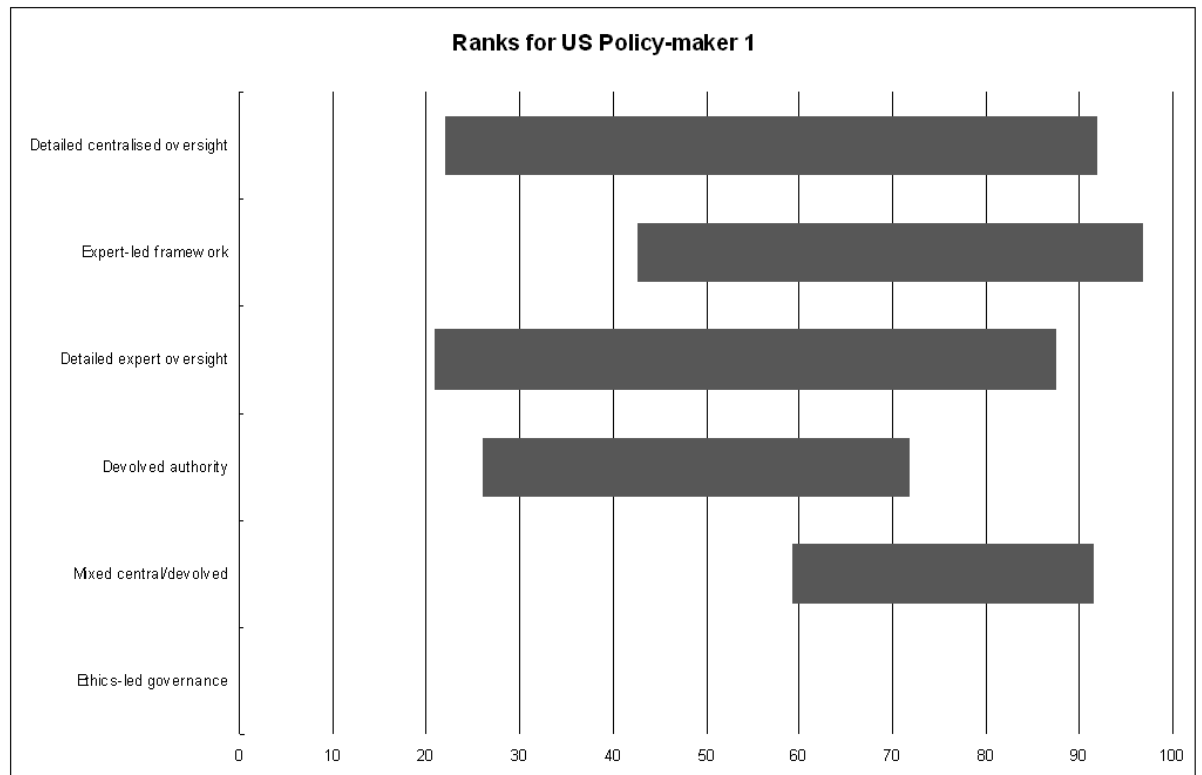
Ranks for US Laboratory Scientists

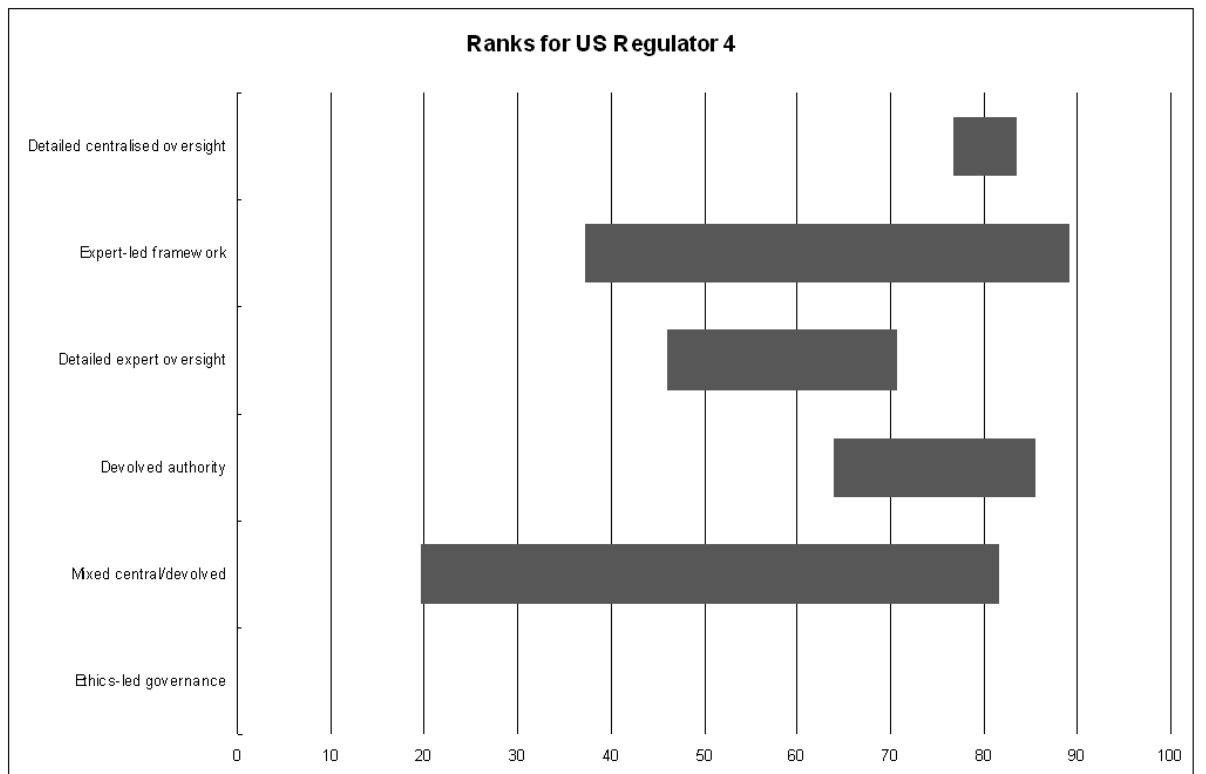
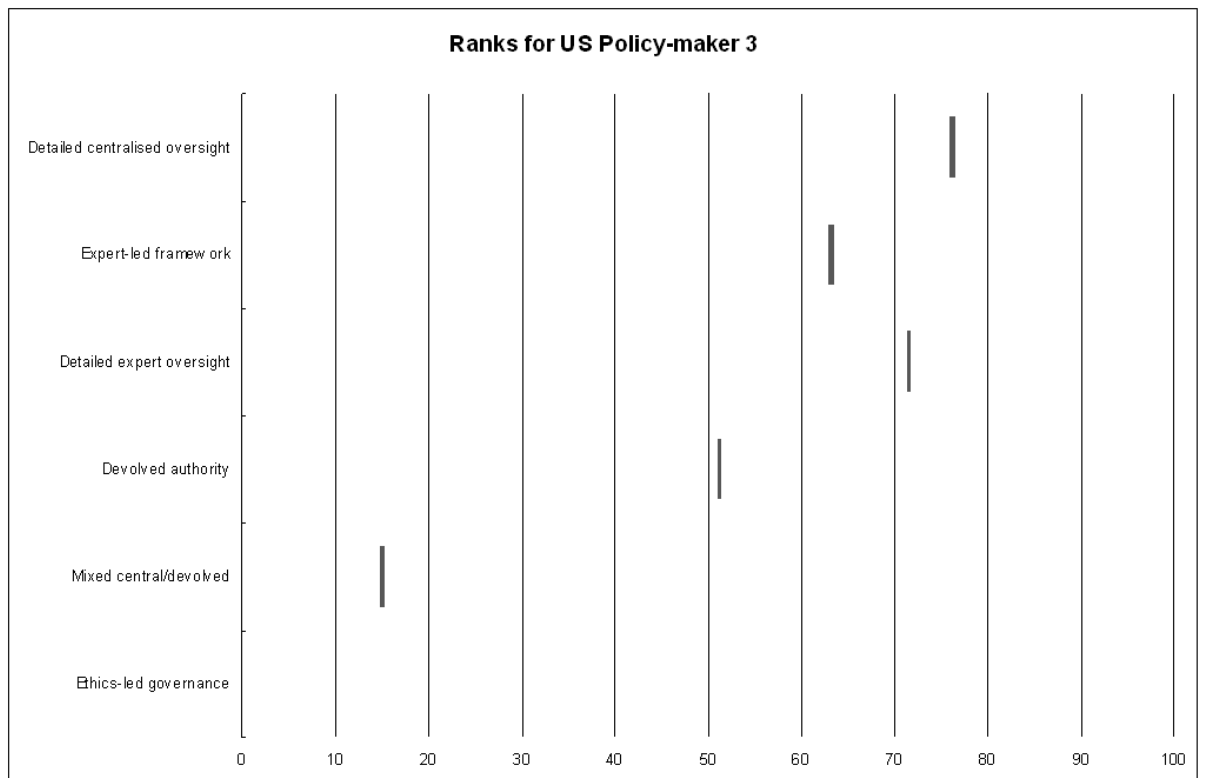


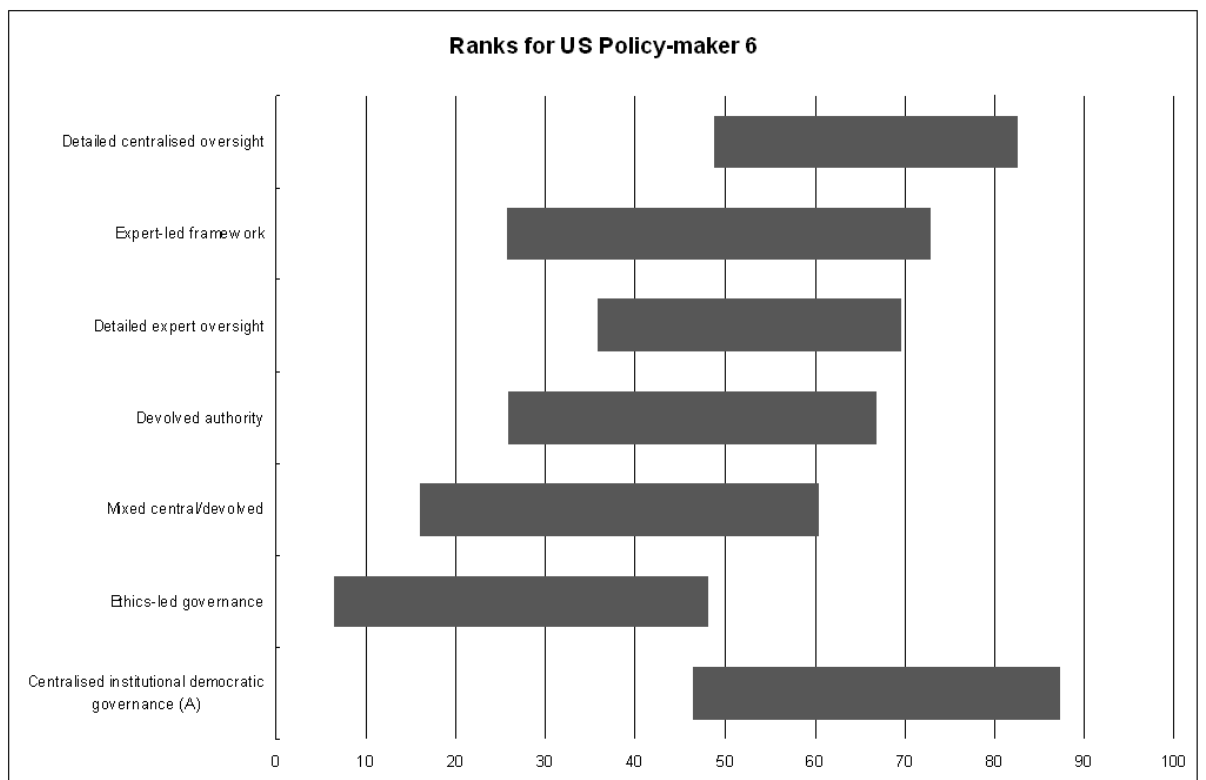
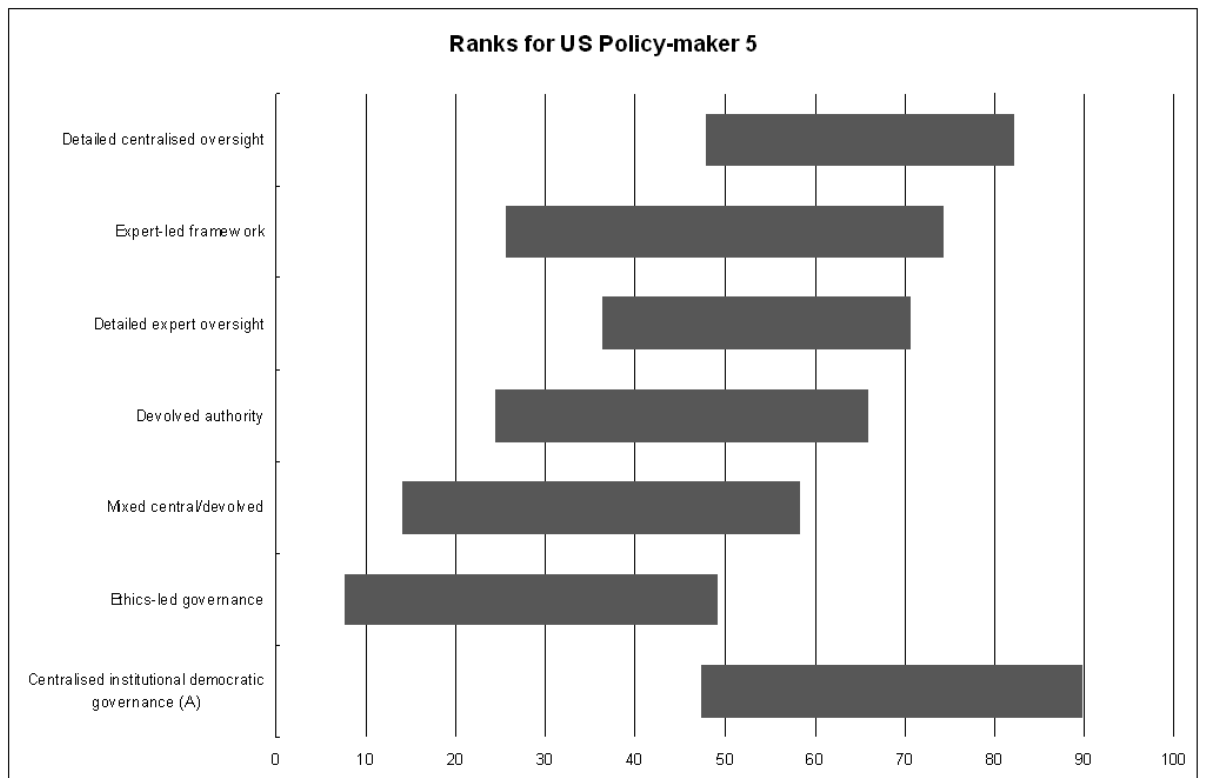


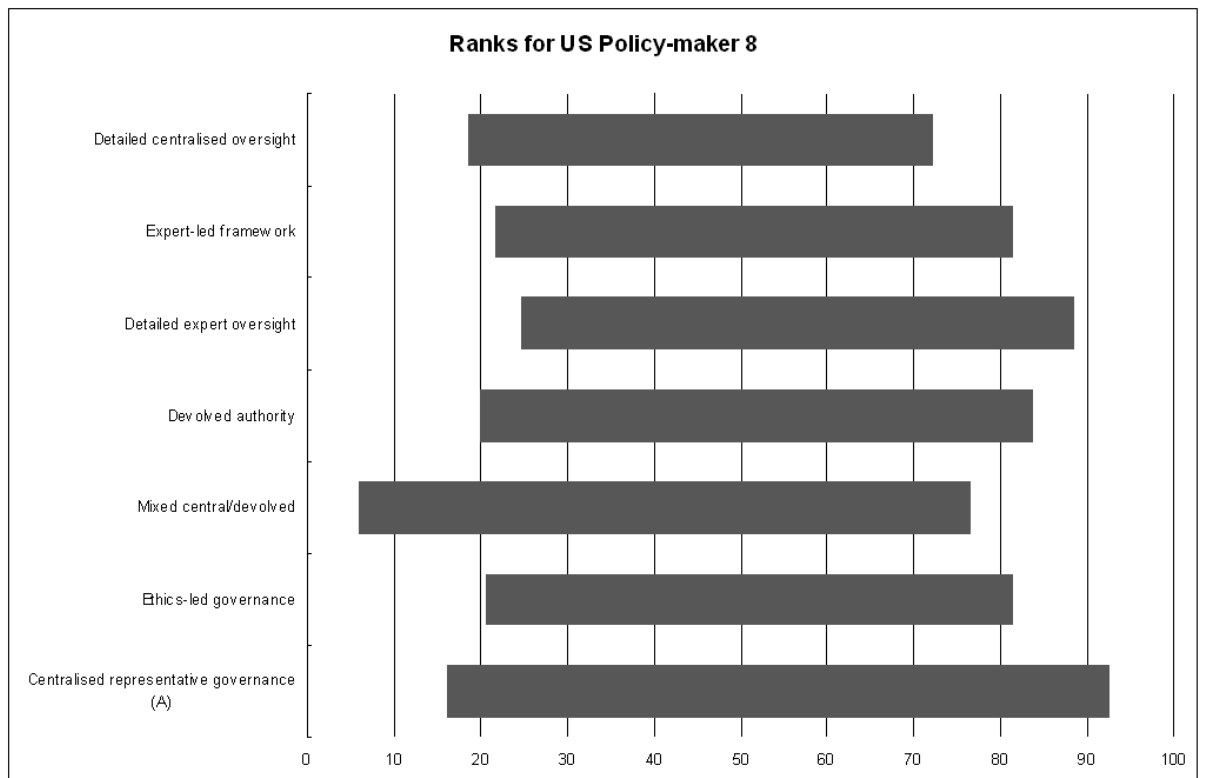
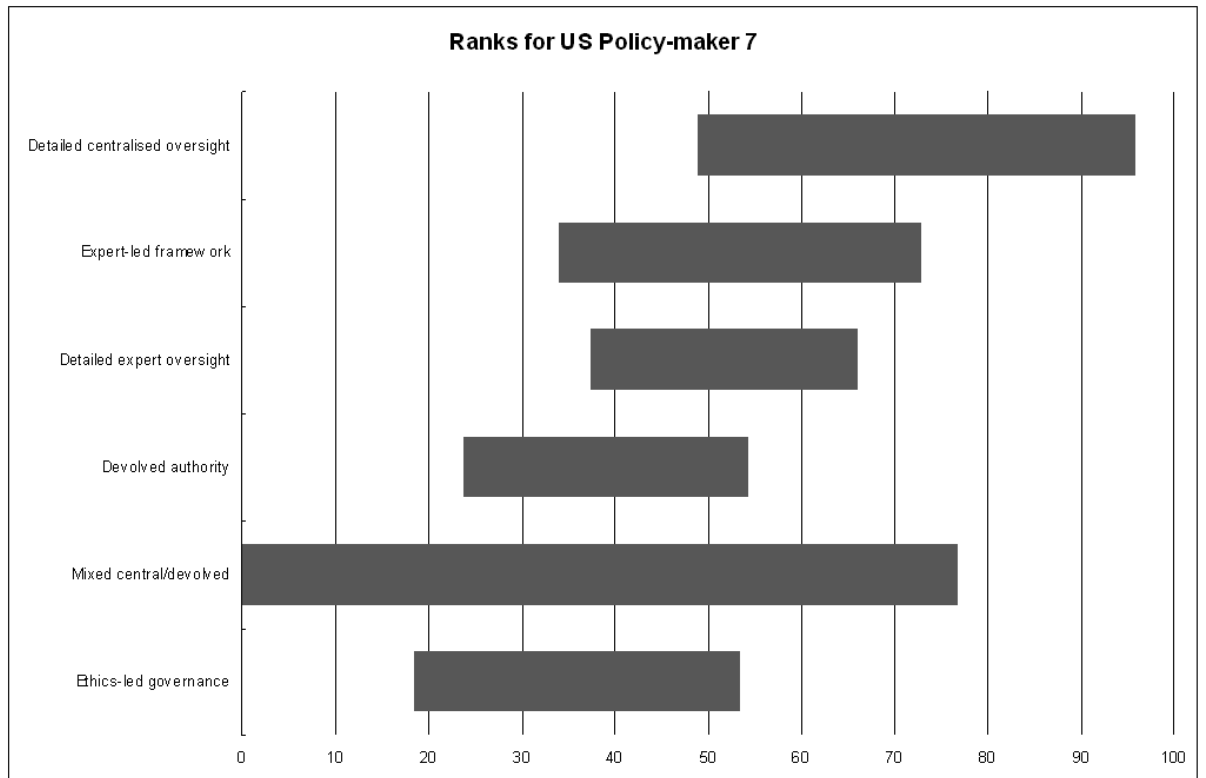


Ranks for US Policy-makers and Regulators

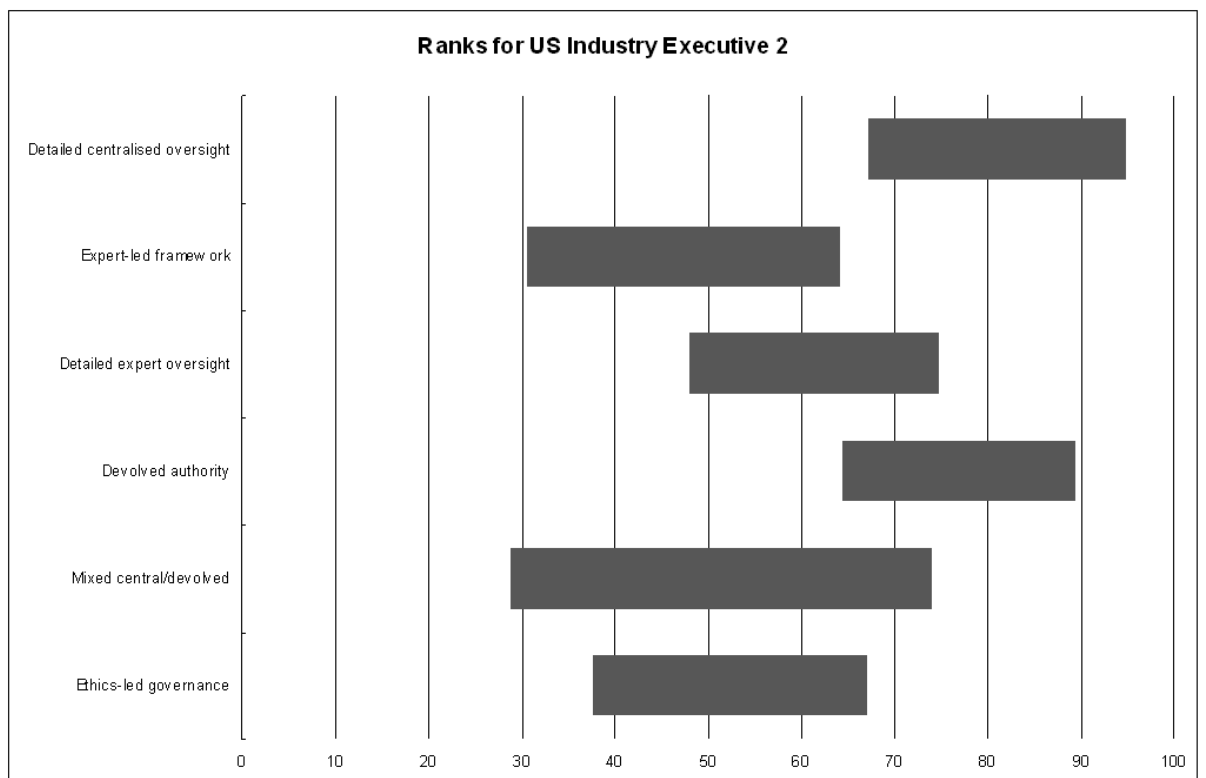
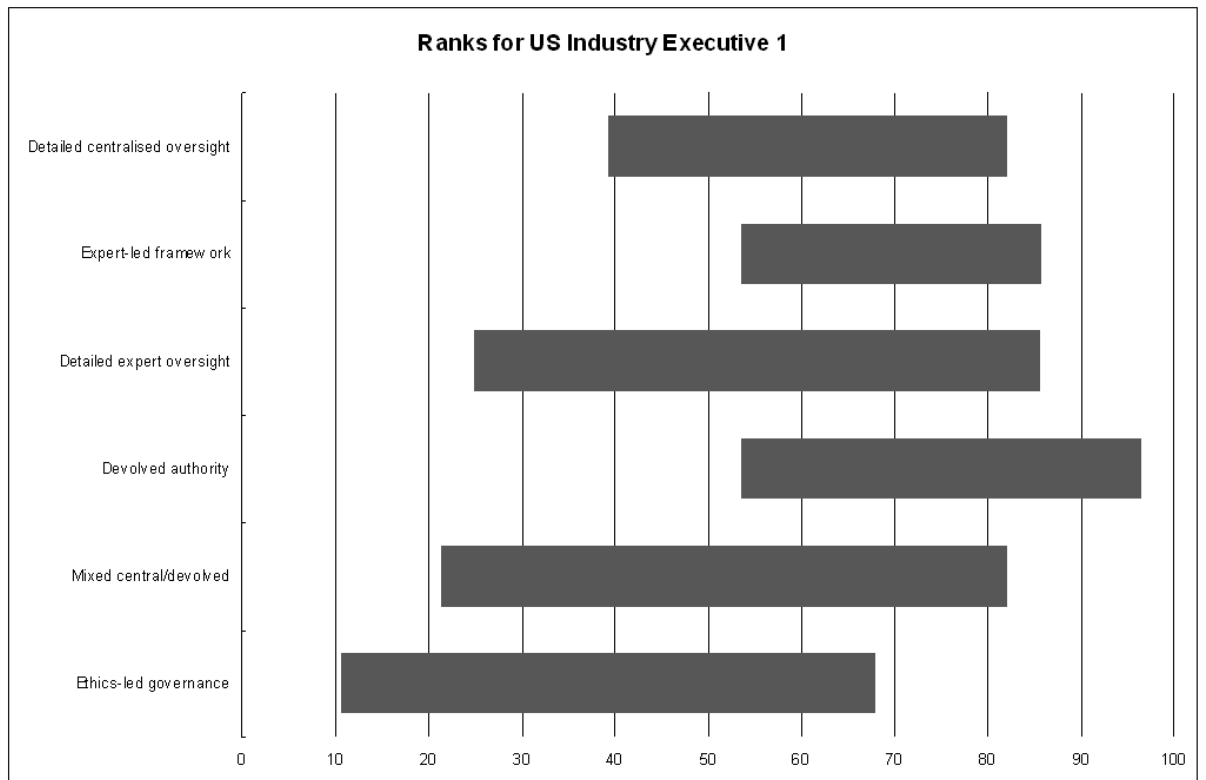


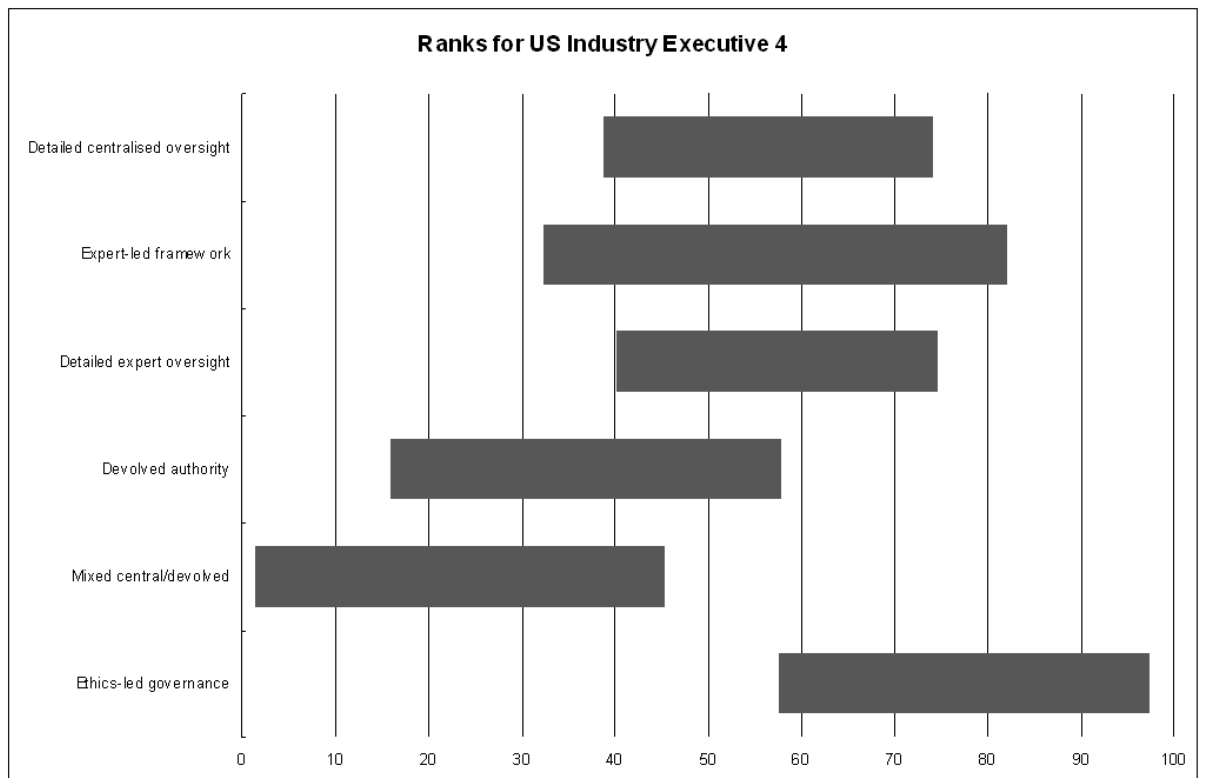
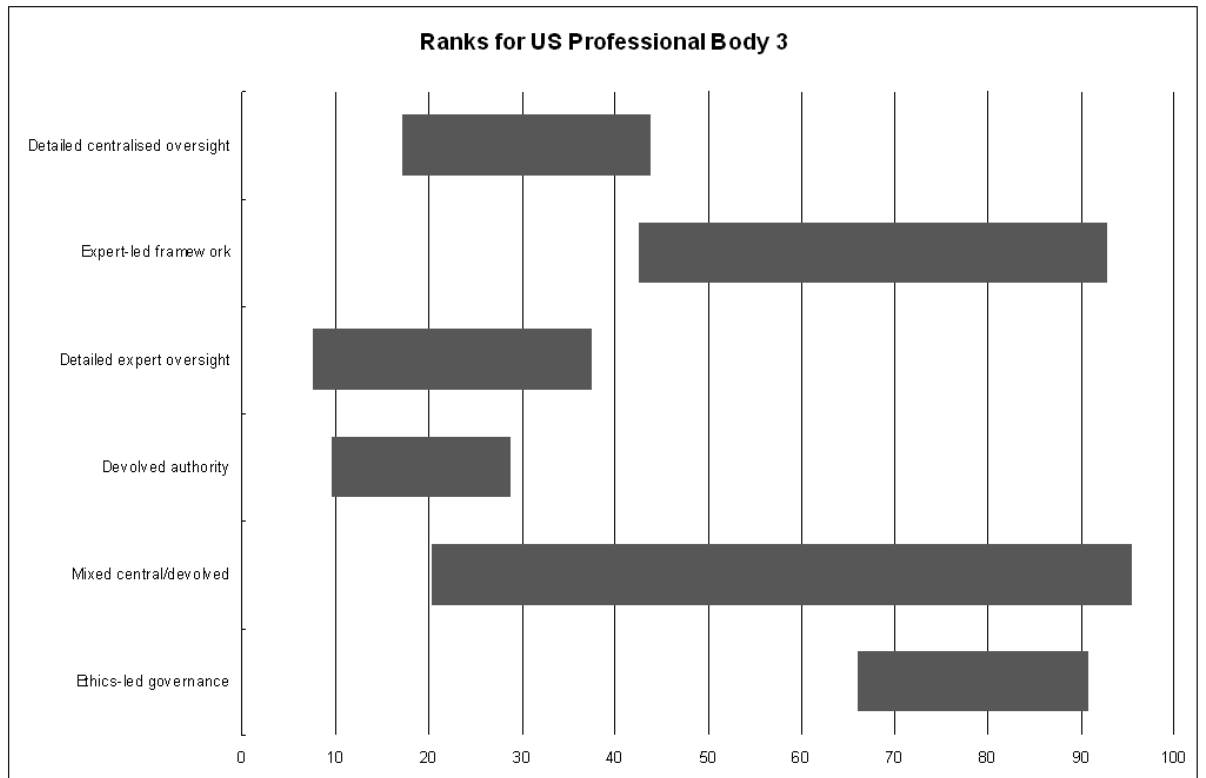


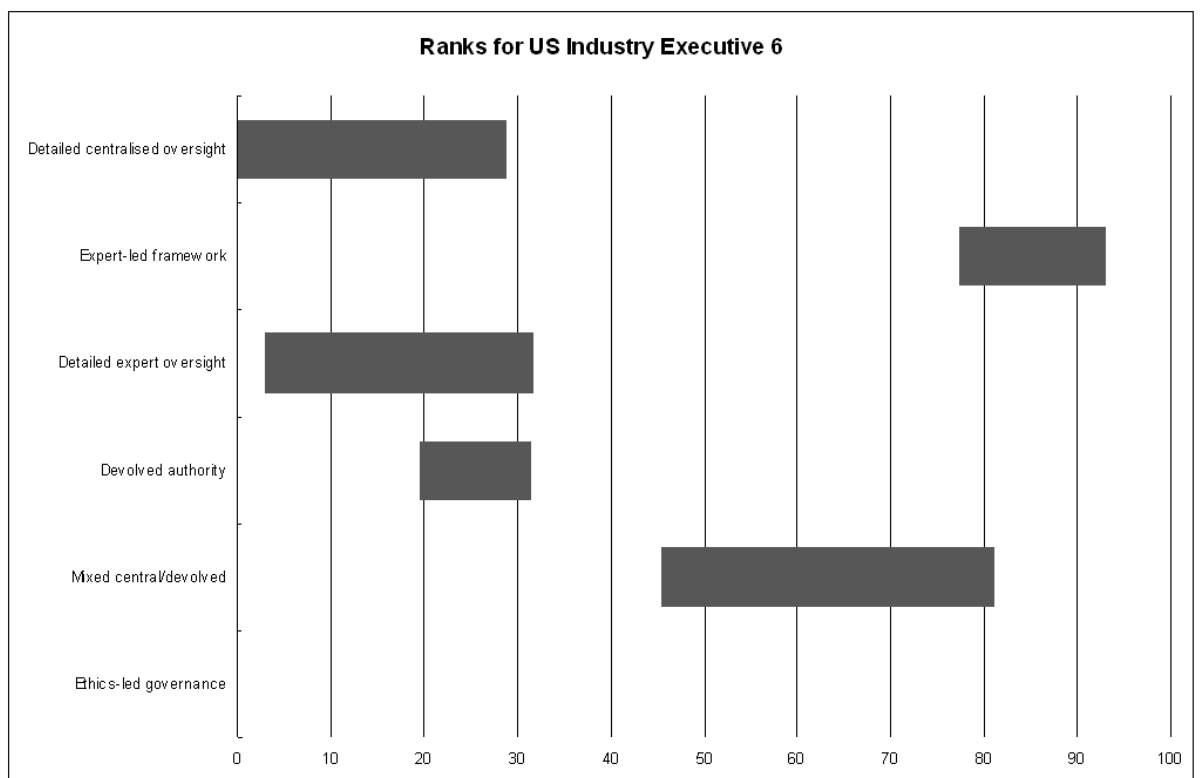
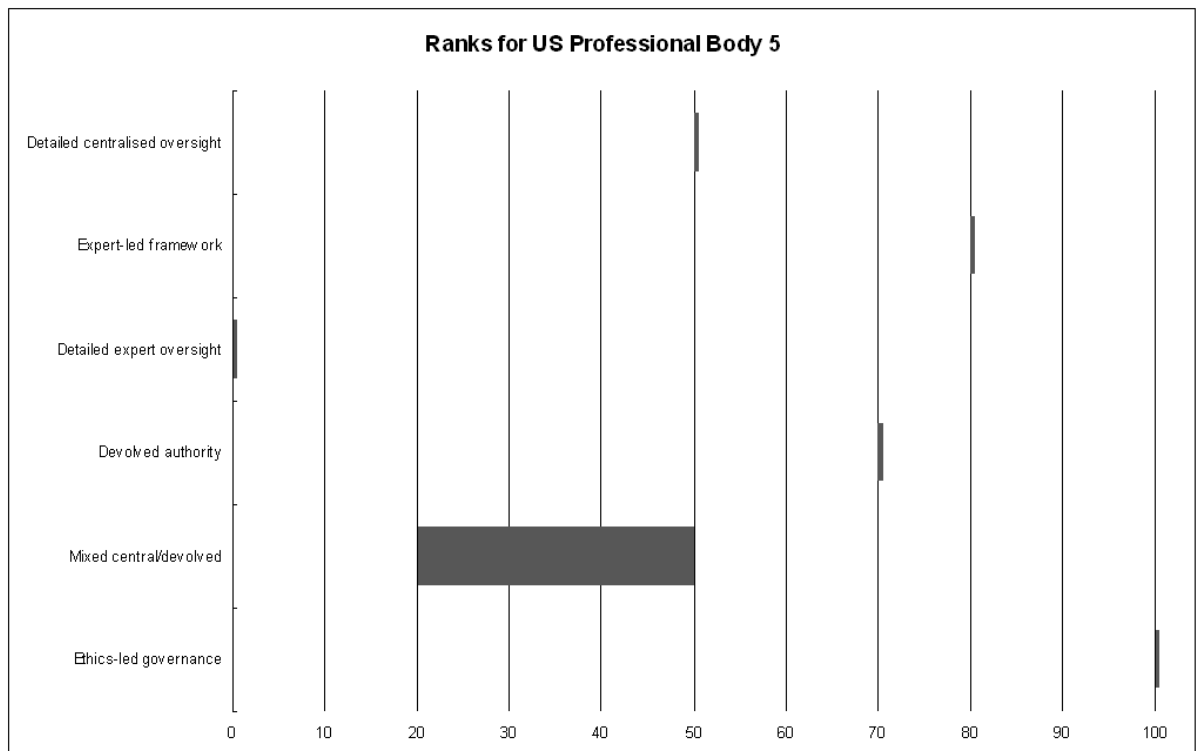




Ranks for US Industry and Professional Body Executives







Annex G – MCM Algorithms

Normalisation and Aggregation Procedures in MC-Mapper

The Multicriteria Mapping methodology makes use of a normalising formula to produce the policy option performance ranks.¹⁶⁴ This employs a ‘linear additive weighting’ mathematical model based on the simple weight average of option performance:

$$r_i = \sum_c s_{ic} \cdot w_c$$

This equation means that the overall performance rank obtained for the i^{th} choice option (r_i) is the sum of the performance scores determined for that option under the c^{th} appraisal criterion (s_{ic}) each multiplied by the importance weighting on that criterion (w_c). The scores are normalised such that:

$$s_{ic} = (m_{ic} - m_{c,\min}) / \sum (m_{c,\max} - m_{c,\min})$$

This equation means that the performance score for the i^{th} choice option under the c^{th} appraisal criterion (s_{ic}) is the ratio of the difference between the performance measure determined for that option (m_{ic}) and that for the lowest-performing option ($m_{c,\min}$) with the difference between the performance measures determined for the highest - ($m_{c,\max}$) and lowest - ($m_{c,\min}$) performing options under that criterion.

Calculation of Outputs in MCM Analysis

The following sequence of steps provides a narrative explanation of the successive steps followed by the MCM Analyst software in calculating the different quantitative charts used in an MCM analysis. They are described verbally for clarity. The initial calculation steps are as follows:

- 1 *for each participant in the selected perspective and for each criterion in the selected issue:*
- 2 *multiply pessimistic normalised scores by normalised weights (this is 'pessimistic subrank');*
- 3 *multiply optimistic normalised scores by normalised weights (this is 'optimistic subrank');*
- 4 *subtract pessimistic subrank from optimistic subrank (this is 'delta');*

¹⁶⁴ Taken from Stirling, A and Mayer, S. 1999. *Rethinking Risk: A pilot of Multi-Criteria Mapping of a genetically modified crop in agricultural systems in the UK*. Falmer: University of Sussex. Pp: Annex 3.

- 5 *sum half delta with pessimistic subrank (this is 'median');*
- 6 *divide delta by median (this is '**ratio uncertainty**').*

In order to calculate the **mean ratio uncertainty** (the measure of uncertainty according to the ratio of the absolute difference between optimistic and pessimistic scores to the underlying values of the scoring ranges), the following additional steps are taken (indicated in successive numerical order to those above):

- 7 *across each criterion in the selected issue and across all participants in the selected perspective:*
- 8 *take mean of ratio uncertainties (this is '**mean ratio uncertainty**').*

From here, **mean interval uncertainty** (the absolute scale of the difference between mean optimistic and mean pessimistic scores) is calculated by:

- 9 *across each criterion in the selected issue and across all participants in the selected perspective:*
- 10 *take mean delta (this is '**mean interval uncertainty**').*

Finally, **mean ambiguity** (the measure of how much individuals within a perspective disagree with each other) is calculated as follows:

- 11 *across each criterion in the selected issue and across all participants in the selected perspective:*
- 12 *take mean of pessimistic subranks (this is 'mean pessimistic subrank');*
- 13 *take mean of optimistic subranks (this is 'mean optimistic subrank');*
- 14 *subtract mean pessimistic subrank from mean optimistic subrank (this is '**mean ambiguity**').*

Annex H – Table of all Multicriteria Mapping criteria

Table H.1: Table of all criteria defined in the MCM interviews

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
1	UK patient advocate 3	Public trust	35.69
2	UK patient advocate 3	Open and transparent framework	21.68
3	UK patient advocate 3	Accountability and monitoring	21.68
4	UK patient advocate 3	Rigid central guidelines	7.29
5	UK patient advocate 3	Flexibility, within rigid central guidelines	7.37
6	UK patient advocate 3	Access to the science	7.29
7	UK Bioethicist 3	Scientific discovery	28.53
8	UK Bioethicist 3	Openness	14.41
9	UK Bioethicist 3	Accountability	16.71
10	UK Bioethicist 3	Public opinion	7.49
11	UK Bioethicist 3	Macro and micro	7.20
12	UK Bioethicist 3	System is respected	18.44
13	UK Bioethicist 3	Administrative burden	7.20
14	UK scientist 1	Biological security	26.85
15	UK scientist 1	Physical security	10.19
16	UK scientist 1	Ethical governance	18.83
17	UK scientist 1	Public confidence	15.74
18	UK scientist 1	Avoiding unnecessary bureaucratic delays	18.52
19	UK scientist 1	Control of commercial exploitation	9.88
20	UK policy-maker 1	Keep science at forefront of research	24.10
21	UK policy-maker 1	Consistency	18.07
22	UK policy-maker 1	Bureaucracy	15.06
23	UK policy-maker 1	Acceptable exploitation	21.39
24	UK policy-maker 1	Prevention of misuse	21.39
25	UK scientist 2	Broad expertise	17.37
26	UK scientist 2	Conservative approach	15.37
27	UK scientist 2	Immune to pressures	17.37
28	UK scientist 2	Progressive and scientifically astute	17.37
29	UK scientist 2	Deliberate	17.37
30	UK scientist 2	Control / Trust	15.17
39	US bioethicist 3	Real public discourse	14.75
40	US bioethicist 3	Ethical oversight	14.75
41	US bioethicist 3	Politics minimized	16.39
42	US bioethicist 3	Religion plays no role	16.39
43	US bioethicist 3	Flexibly accommodate new science	11.48
44	US bioethicist 3	Technology and science friendly	11.48
45	US bioethicist 3	Transparent	14.75
46	US policy-maker 3	Scientific merits of research	20.67
47	US policy-maker 3	Balance of views	20.67
48	US policy-maker 3	Federal oversight	20.67
49	US policy-maker 3	Stability	20.67
50*	US policy-maker 3	Intellectual property	6.98
51	US policy-maker 3	Ownership control	10.34
52	US policy advocate 6	Funding is allowed from any source	24.92

¹⁶⁵ The reader may note that in some cases the numbers skip ahead and that the final Criterion ID is not 310, but 349. This is due to the way the data are loaded into the database and some of the errors and ‘re-loading’ that had to occur. It is not due to omissions of data.

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
53	US policy advocate 6	Presence of a federal framework	20.19
54	US policy advocate 6	Consistency of oversight	18.93
55	US policy advocate 6	Ethical and moral framework	6.62
56	US policy advocate 6	Positive aspects of research brought to forefront	29.34
57	US scientist 5	Responsibility	17.47
58	US scientist 5	Accountability	12.91
59	US scientist 5	Standardised	20.00
60	US scientist 5	Flexibility	12.91
61	US scientist 5	Multiple layers of oversight	16.46
62	US scientist 5	Expert input to policy	20.25
63	US scientist 2	Ethical framework	25.12
64	US scientist 2	High standards of conduct	25.12
65	US scientist 2	Respect for embryo	24.75
66	US scientist 2	Government oversight	25.00
67	US regulator 4	Public legitimacy	28.57
68	US regulator 4	Good science to go forward	28.57
69	US regulator 4	Minimal resources	14.00
70	US regulator 4	Check on bad science	23.00
71*	US regulator 4	Public norms	5.90
72	US industry executive 6	Local control and oversight	18.08
73	US industry executive 6	Flexibility at central level	18.31
74	US industry executive 6	Facilitates science moving forward	18.31
75	US industry executive 6	Ownership	14.65
76	US industry executive 6	Safety is ensured	9.61
77	US industry executive 6	Commercialisation	14.42
78*	US industry executive 6	Minimal levels of oversight	6.64
79	US regulator 2	Constitutional mandate	24.68
80	US regulator 2	Advance research	18.27
81	US regulator 2	High ethical standards	15.06
82	US regulator 2	Issue identification	21.15
83	US regulator 2	Space for public deliberation	11.86
84	US regulator 2	Evaluative function	8.97
97	US patient advocate 5	Non segregation of hESC research	17.42
98	US patient advocate 5	Informed consent framework	26.48
99	US patient advocate 5	Safety and transparency ensured	26.48
100	US patient advocate 5	Public trust and confidence	29.62
Principle	US patient advocate 5	No religion	
101	US bioethicist 1	Meta-guidance	11.57
102	US bioethicist 1	Local and multi-disciplinary expert guidance	24.04
103	US bioethicist 1	Feedback	17.80
104*	US bioethicist 1	Collaboration	5.04
105	US bioethicist 1	Flexibility	17.51
106	US bioethicist 1	Pluralistic approach	24.04
107	US policy-maker 1	Science	21.05
108	US policy-maker 1	Respectful of multiple views	21.05
109	US policy-maker 1	Flexibility	15.79
110	US policy-maker 1	Accountability	16.84
111	US policy-maker 1	Transparency	12.63
112	US policy-maker 1	Local oversight	12.63
113	US patient advocate 4	Flexible response to evolving technologies	12.15
114	US patient advocate 4	Speed of approval	15.79
115	US patient advocate 4	Consistency of interpretation	27.94
116	US patient advocate 4	Diverse composition of approving body	19.84
117	US patient advocate 4	Stable research environment	24.29
118	UK regulator 4	Public confidence	19.00
119	UK regulator 4	Transparency	16.33

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
120	UK regulator 4	Accountability	16.33
121	UK regulator 4	Broad expertise	16.33
122	UK regulator 4	Flexibility	16.33
123	UK regulator 4	Feasibility and Proportionate Response	16.33
124	UK bioethicist 4	Scientific progress	22.39
125	UK bioethicist 4	Minimal bureaucracy	22.39
126	UK bioethicist 4	Public confidence is fostered	14.93
127	UK bioethicist 4	Ethical consistency	20.52
128	UK bioethicist 4	Pragmatic	18.66
129*	UK bioethicist 4	Necessary and useful engagement	1.2
130	UK policy opposition 1	Expertise	14.42
131	UK policy opposition 1	Engagement	20.06
132	UK policy opposition 1	Framing	19.75
133	UK policy opposition 1	Funding	14.73
134	UK policy opposition 1	Openness	18.50
135	UK policy opposition 1	Timing	12.54
136	UK policy-maker 2	Respect for embryo	22.73
137	UK policy-maker 2	Embryo research has potential to benefits others	22.73
138	UK policy-maker 2	Egg donation	22.73
139	UK policy-maker 2	Proportionate regulation	18.18
140	UK policy-maker 2	Scientific creativity is fostered	13.64
141	US policy advocate 3	Objective neutrality	17.27
142	US policy advocate 3	Ethical guideline of framework	9.60
143	US policy advocate 3	Leadership	19.19
144	US policy advocate 3	Funding	9.60
145	US policy advocate 3	Science dictates policy	17.47
146	US policy advocate 3	Research is advanced	15.00
147*	US policy advocate 3	Education	11.52
148	UK bioethicist 1	Accountability	22.16
149	UK bioethicist 1	Flexibility	20.50
150	UK bioethicist 1	Consistency	13.85
151	UK bioethicist 1	Support and trust fostered	27.70
152	UK bioethicist 1	Responsiveness	15.79
153	UK professional body 6	Quality assurance	29.08
154	UK professional body 6	Acceptability	18.30
155	UK professional body 6	Transparency	18.30
156	UK professional body 6	Streamlined and minimal bureaucracy	18.30
157	UK professional body 6	Globalisation	16.01
158	UK professional body 5	Enables scientific progress	20.83
159	UK professional body 5	Regulations ensure safety and research ethics	20.83
160	UK professional body 5	Process is transparent	14.58
161	UK professional body 5	Have multiple types of expertise	14.58
162	UK professional body 5	Access	14.58
163	UK professional body 5	Consistency	14.58
164	US bioethicist 2	Politics	22.73
165	US bioethicist 2	Ethics	18.18
166	US bioethicist 2	Risks	18.18
167	US bioethicist 2	Globalisation	15.91
168	US bioethicist 2	Employment	11.36
169	US bioethicist 2	Ownership	13.64
170	UK policy-maker 3	Balanced	23.53
171	UK policy-maker 3	Transparency	17.65
172	UK policy-maker 3	Responsible	23.53
173	UK policy-maker 3	Flexibility	5.88
174	UK policy-maker 3	Objectivity	23.53
175	UK policy-maker 3	Compliance	5.88

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
176	UK patient advocate 4	Public acceptance	13.43
177	UK patient advocate 4	Science progress	22.00
178	UK patient advocate 4	Compliance	4.84
179	UK patient advocate 4	Ethics	24.86
180	UK patient advocate 4	Expertise	21.72
181	UK patient advocate 4	Transparency	13.15
182	UK industry executive 2	Ethics	15.22
183	UK industry executive 2	Transparency	21.74
184	UK industry executive 2	Education	19.57
185	UK industry executive 2	Responsibility	17.39
186	UK industry executive 2	Regulation	8.70
187	UK industry executive 2	Feasibility	17.39
188	UK bioethicist 2	Public debate open	20.00
189	UK bioethicist 2	Expertise	20.00
190	UK bioethicist 2	Flexibility	19.80
191	UK bioethicist 2	Moral sensitivity	20.00
192	UK bioethicist 2	Encouraging of science	20.00
193	UK scientist 3	Reasonable balance	33.33
194	UK scientist 3	Support from stakeholders	25.00
195	UK scientist 3	Fairness through consistency	25.00
196	UK scientist 3	Opportunity to express views	16.67
197	UK policy opposition 2	Knowledge	23.68
198	UK policy opposition 2	Expertise	15.79
199	UK policy opposition 2	Legitimacy	26.32
200	UK policy opposition 2	International sensitivity	7.89
201	UK policy opposition 2	Morality and ethics	26.32
202	UK industry executive 3	Smooth regulatory response	31.03
203	UK industry executive 3	Flexibility	17.24
204	UK industry executive 3	Breadth of expertise	34.48
205	UK industry executive 3	Accountability	17.24
206	US scientist 1	Funding	15.66
207	US scientist 1	Efficiency of decision-making	19.57
208	US scientist 1	Harmonisation	19.57
209	US scientist 1	Freedom from meddling	17.61
210	US scientist 1	Education	5.87
211	US scientist 1	Transparency	6.07
212	US scientist 1	Trust	15.66
220	US policy opposition 2	Reflective expertise	27.65
221	US policy opposition 2	Adaptability of framework	16.71
222	US policy opposition 2	Effective oversight (with minimal bureaucracy)	27.68
223	US policy opposition 2	Address marginalised communities	27.96
224	US industry executive 2	Clarity of the rules	20.47
225	US industry executive 2	Clear authority	16.08
226	US industry executive 2	Predictability	26.32
227	US industry executive 2	Participation in rule-making	8.48
228	US industry executive 2	Extent of freedom to act	28.65
229	US professional body 5	Informed scientific input	20.00
230	US professional body 5	Advance and progress the research	20.00
231	US professional body 5	Guidelines	20.00
232	US professional body 5	Insulation from politics	20.00
233	US professional body 5	Advancing therapies	20.00
234	US policy-maker 8	Engender public trust - processes	22.22
235	US policy-maker 8	Engender public trust - policies that protect the public and individuals	22.22
236	US policy-maker 8	Presence of effective oversight and enforcement mechanisms	22.00

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
237	US policy-maker 8	Supporting meritorious science	22.22
238	US policy-maker 8	Flexibility	11.11
245	US bioethicist 5	Defence of human life and dignity	30.30
246	US bioethicist 5	Advance scientific research and medical treatment	24.24
247	US bioethicist 5	Effectiveness	12.12
248	US bioethicist 5	Avoids divisiveness	18.18
249	US bioethicist 5	Resolution through democratic processes	15.15
250	US patient advocate 1	Non-discriminatory	6.23
251	US patient advocate 1	Meeting society's needs and interests	32.79
252	US patient advocate 1	Science is advanced	26.23
253	US patient advocate 1	Ethical compliance	26.23
254	US patient advocate 1	Congressional oversight	3.28
255	US patient advocate 1	Flexibility and efficiency	5.25
256	US professional body 3	Flexibility of system to allow scientific progress	24.04
257	US professional body 3	Consistency among research tools	8.89
258	US professional body 3	Vulnerability to political winds	13.22
259	US professional body 3	Public input	11.54
260	US professional body 3	Institutional variation	9.38
261	US professional body 3	Appropriateness of oversight body	9.62
262	US professional body 3	Credibility and acceptability, consent of the governed	18.99
263	US professional body 3	Place for State role	4.33
264	US policy-maker 6	Transparency	19.61
265	US policy-maker 6	Uniformity and consistency	19.61
266	US policy-maker 6	Fosters scientific breakthrough	14.71
267	US policy-maker 6	Economic return to state	9.80
268	US policy-maker 6	Effectiveness	17.65
269	US policy-maker 6	Efficiency	18.63
270	US policy-maker 5	Transparency	15.84
271	US policy-maker 5	Uniformity and consistency	15.84
272	US policy-maker 5	Fosters scientific breakthrough	18.81
273	US policy-maker 5	Economic return to state	9.90
274	US policy-maker 5	Effectiveness	19.80
275	US policy-maker 5	Efficiency	19.80
276	US bioethicist 4	Ethics	21.74
277	US bioethicist 4	Progress	19.57
278	US bioethicist 4	Justice	21.74
279	US bioethicist 4	Science	19.57
280	US bioethicist 4	Regulation	17.39
281	US scientist 3	Science advances	20.12
282	US scientist 3	Flexibility	19.89
283	US scientist 3	Safety	29.84
284	US scientist 3	Morality, religion and ethics are discussed	20.23
285	US scientist 3	Realistic expectations about feasibility of the science	9.92
286	US scientist 4	Expertise	9.14
287	US scientist 4	Society sets the standards	9.14
288	US scientist 4	Balance of expertise and a society	18.28
289	US scientist 4	Enforceable ethical guidelines	18.28
290	US scientist 4	International harmonisation	18.28
291	US scientist 4	Flexibility of oversight	12.25
292	US scientist 4	Advance biomedical research	14.63
293	US industry executive 4	Impact on public health	28.93
294	US industry executive 4	Responsiveness to new knowledge	20.66
295	US industry executive 4	Balance economic cost/benefit	8.26
296	US industry executive 4	Scientific integrity	33.06
297	US industry executive 4	Public opinion	9.09

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
298	US policy-maker 7	Broad representation of public and balanced selection of decision makers	28.07
299	US policy-maker 7	Flexibility	22.81
300	US policy-maker 7	Transparency	14.04
301	US policy-maker 7	Harmonisation	7.02
302	US policy-maker 7	Effective implementation, oversight and monitoring	28.07
303	UK scientist 7	Public involvement	20.00
304	UK scientist 7	Advancing the science to full potential	20.00
305	UK scientist 7	Openness of scientific discovery	20.00
306	UK scientist 7	Workable legislation	20.00
307	UK scientist 7	Responsible management of expectations	20.00
308	UK patient advocate 5	Accommodate uncertainty	18.69
309	UK patient advocate 5	Achieve balance in research aims	14.95
310	UK patient advocate 5	Instils real trust	23.36
311	UK patient advocate 5	Grounded in good science	28.04
312	UK patient advocate 5	Honouring the gift	14.95
313	UK scientist 6	Clear rules	19.23
314	UK scientist 6	Responsiveness	19.23
315	UK scientist 6	Public involvement	9.62
316	UK scientist 6	Oversight done by multi-disciplinary experts	13.46
317	UK scientist 6	Safety and efficacy	19.23
318	UK scientist 6	Informed consent to the process of deriving stem cell lines	19.23
319	UK scientist 5	Get the science right	31.25
320	UK scientist 5	Responsibility	20.83
321	UK scientist 5	Fosters trust	20.83
322	UK scientist 5	Strong regulation	12.05
323	UK scientist 5	Politics	4.17
324	UK scientist 5	Leadership	10.42
325	UK scientist 4	Enables quality science	60.00
326	UK scientist 4	Cost-effectiveness and efficiency	10.00
327	UK scientist 4	Flexible to change	25.04
328	UK scientist 4	Transparency	5.00
Principle	UK scientist 4	Representation	
Principle	UK scientist 4	Alignment to the laws of the country	
329	UK professional body 4	Enables innovative research	21.98
330	UK professional body 4	Representative of community at large	13.19
331	UK professional body 4	Engagement	16.48
332	UK professional body 4	Protection (safety)	15.38
333	UK professional body 4	Protection (morality)	10.99
334	UK professional body 4	Achievable	21.98
335	UK industry executive 1	Multidisciplinary expertise	22.22
336	UK industry executive 1	Formality of the governance structure	22.22
337	UK industry executive 1	Appeals process	11.11
338	UK industry executive 1	Incentivises research	22.22
339	UK industry executive 1	Consistency with public policy and public opinion	22.22
340	UK policy opposition 6	Democratic principle of control	21.05
341	UK policy opposition 6	Openness	15.79
342	UK policy opposition 6	Inclusion of 'democratic' ethics	15.79
343	UK policy opposition 6	Broad public representation	15.79
344	UK policy opposition 6	Exclusion of commercial interests	15.79
345	UK policy opposition 6	Quality of scientific advice	15.79
346	US industry executive 1	Freedom to perform research	42.89
347	US industry executive 1	Adherence to democratic principles	14.37
348	US industry executive 1	Consistency of interpretation	14.15
349	US industry executive 1	Flexibility	28.59

Criterion ID ¹⁶⁵	Participant	Criterion Name	Criterion Weight
	UK patient advocate 7**	Public involvement	
	UK patient advocate 7	Expert evaluation	
	UK patient advocate 7	Legislative framework	
	UK patient advocate 7	Central licensing authority	
	UK patient advocate 7	Facilitates collaboration	
	UK patient advocate 7	Local oversight	
	UK patient advocate 7	Transparency	
	UK patient advocate 7	Equality	
	UK policy opposition 8**	Respect for human life and protection of the weak	
	UK policy opposition 8	Respect for cultural pluralism	
	UK policy opposition 8	Strong regulations	
	UK policy opposition 8	Central research authority	
	UK policy opposition 8	Advance the science responsibly	
	UK policy opposition 8	Investment	
	UK policy opposition 8	Caution	

*Criteria indicated with an asterisk next to their Criterion ID are those that were weighted, but options were not evaluated under them.

**These two participants only defined criteria and did not complete a full MCM interview.

Annex I – Additional Multicriteria analysis and charts for UK and US perspectives as presented in Chapter 6

Weightings for the issues presented in Chapter 6

The table below provides a summary of the average weightings across all the issues presented in Chapter 6, namely, ‘advances the science’, ‘qualities of deliberative activities’, ‘role of the public’ and ‘nature of expertise’. The reader is referred to the text in Chapter 6 for the significance of the weightings in relation to the analysis presented.

Table I.1: Table of average weightings for criteria

Criteria Type	Criteria of this type among 147 total criteria defined by a total of 27 UK participants?	Criteria of this type among 163 total criteria defined by a total of 30 US participants?	Criteria of this type among 310 total criteria defined by a total of 57 US and UK participants
Advances the science	44 criteria defined by 23 participants Mean weighting: 32.5%	71 criteria defined by 30 participants Mean weighting: 44%	115 criteria defined by 53 participants Mean weighting: 38%
Qualities of deliberative activities	55 criteria defined by 25 participants Mean weighting: 38%	39 criteria defined by 25 participants Mean weighting: 24%	94 criteria defined by 50 participants Mean weighting: 31%
Role of the public	35 criteria defined by 21 participants Mean weighting: 24%	23 criteria defined by 19 participants Mean weighting: 13%	58 criteria defined by 40 participants Mean weighting: 18%
Nature of expertise	21 criteria defined by 16 participants Mean weighting: 15%	16 criteria defined by 12 participants Mean weighting: 11%	35 criteria defined by 21 participants Mean weighting: 13%

US and UK perspectives under ‘role of the public’ criteria

In Chapter 6, Section 6.3, we point out certain features of uncertainty and ambiguity in the performance rankings for UK and US perspectives under the ‘role of the public’ criteria. The charts showing how this was analysed are presented below. Figure I.1 and I.2 below show the mean ambiguity and mean interval uncertainty rankings for US perspectives under the ‘role of the public’ criteria. The mean ambiguity rankings indicate the amount of disagreement between individuals within the perspective. We can see from Figure I.1 that the ambiguity is highest for the mixed central/devolved option, but otherwise is fairly standard (between 6-8 base points) for the other options. A similar pattern is found for the mean interval uncertainty rankings in Figure I.2, leading us to be reasonably confident that both uncertainty and ambiguity are affecting the larger performance ranking intervals fairly equally.

Figure I.1: Mean ambiguity rankings for US perspectives for ‘role of the public’ criteria

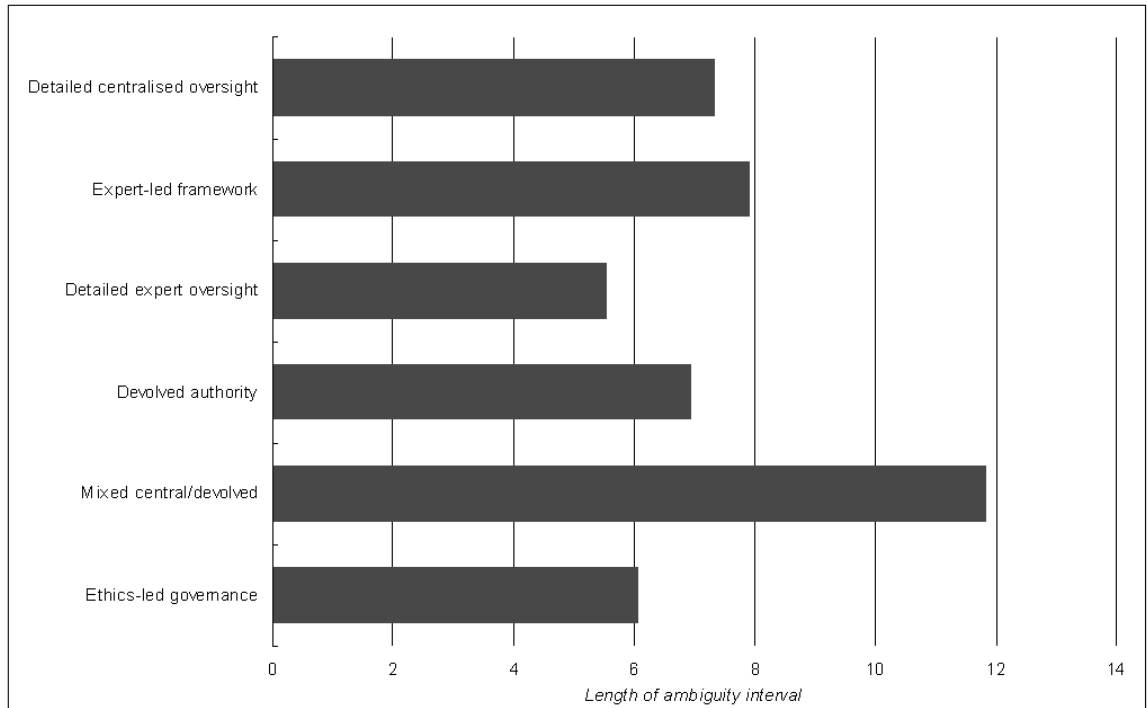
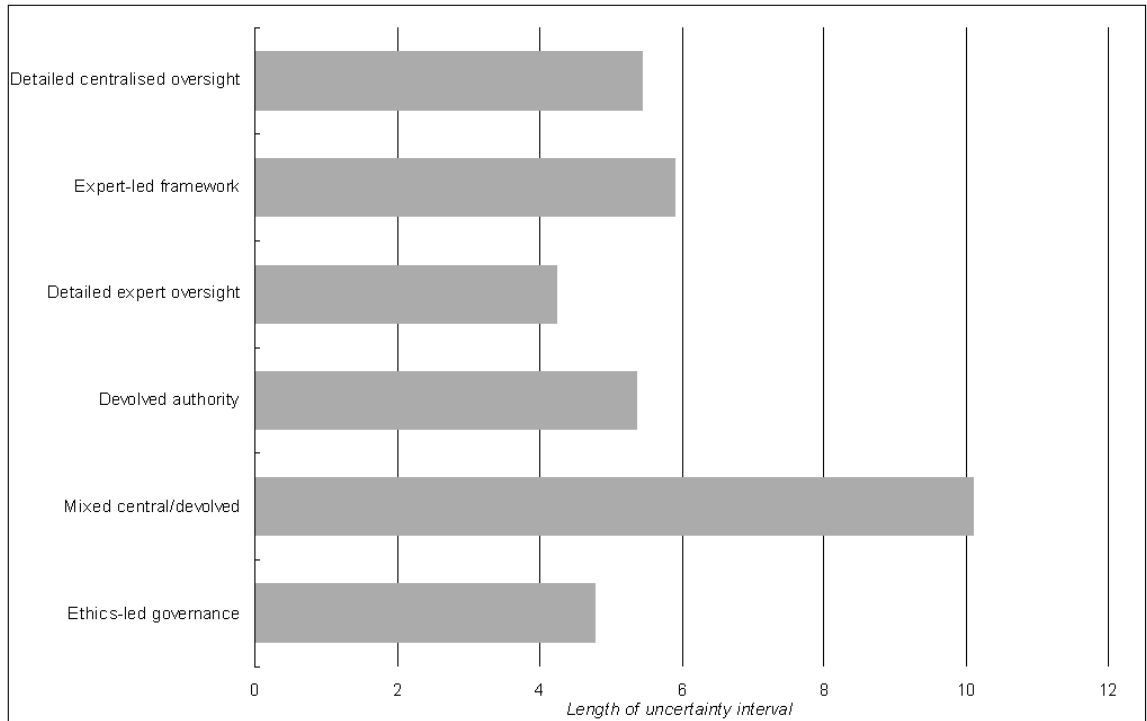


Figure I.2: Mean interval uncertainty rankings for US perspectives and ‘role of the public’ criteria



Figures I.3 and I.4, below, show the same sets of rankings for mean ambiguity and mean interval uncertainty, but for UK perspectives. The same conclusions as above

are drawn about the relative influence of ambiguity and uncertainty on the option performance rankings. However, here we compare the charts for the UK perspectives with those of the US perspectives. We see that there is a much more even expression of ambiguity and uncertainty across all the options for UK perspectives. There is also, on average, higher ambiguity expressed by UK perspectives than US perspectives, while the relative uncertainty expressed by both groups is fairly similar (with the exception of the mixed central/devolved option for US perspectives). These charts thus confirm the claims in Chapter 6 that UK participants express greater ambiguity relative to each other than US participants when evaluating the options under the ‘role of the public’ criteria.

Figure I.3: Mean ambiguity rankings for UK perspectives for ‘role of the public’ criteria

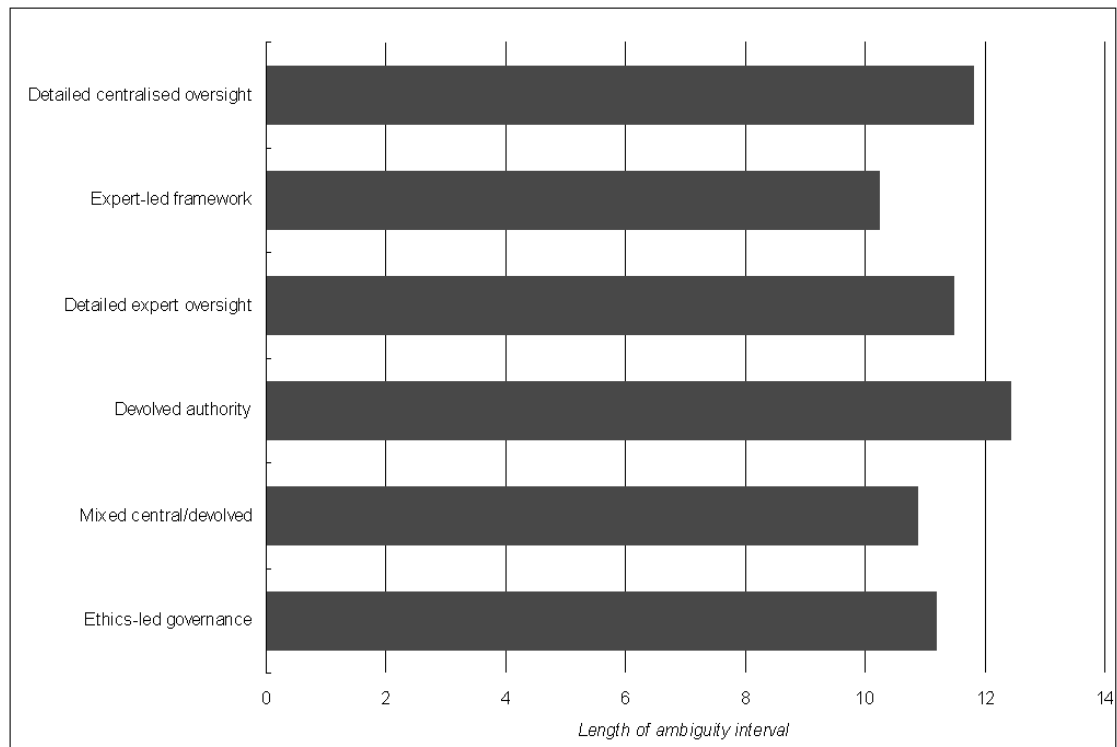
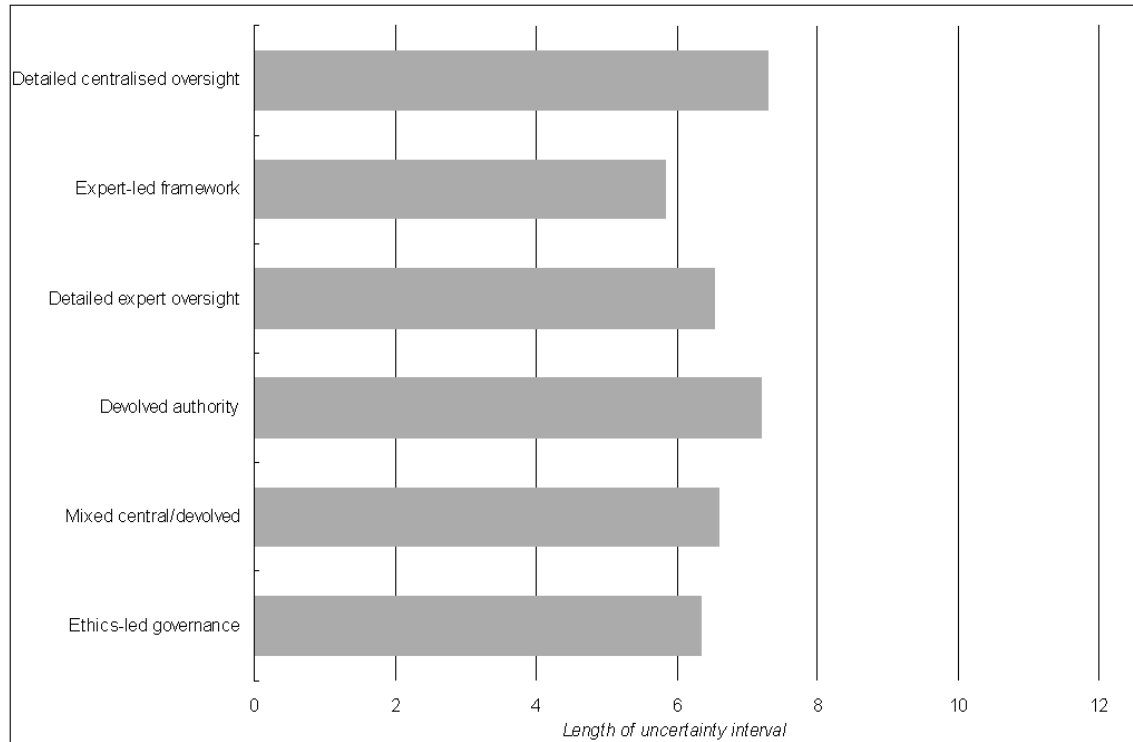


Figure I.4: Mean interval uncertainty rankings for UK perspectives and ‘role of the public’ criteria



Deliberations and trust rankings

In Chapter 6 the normative and instrumental motivations underlying criteria about the ‘nature of deliberations’ and ‘trust’, respectively, were discussed. The evaluations of these issues are presented in more detail there, but the performance rankings are shown in this Annex. First, though, we will briefly describe the definition of each issue as it was used in the MCM analysis.

Deliberations (Normative): Criterion in this issue address exactly how and why expert or public input should be constructed in order to ensure sound democratic processes are followed. Criteria in this issue distinctly refer to particular characteristics and qualities of deliberations that must be present as a matter of principle. They are, in and of themselves, simply right elements of good governance and are discussed without reference to the ends they may achieve, simply the means by which they are implemented.

Trust (Instrumental): This issue is characterised by criteria that appeal to fostering and building public trust and confidence in the governance system. Criteria are used in evaluation in such a way as to determine how much a particular option or governance configuration is going to instil or foster strong feelings of public trust and confidence in either the regulator, the system, the science itself, and so on. Thus, the issue is clearly focussed on the instrumental, outcome-based concerns of achieving trust in whatever governance process is in place.

The two figures below show the rankings and respective counts of criteria within each issue.

Figure I.5: Rankings for UK and US perspectives under ‘normative deliberations’ criteria

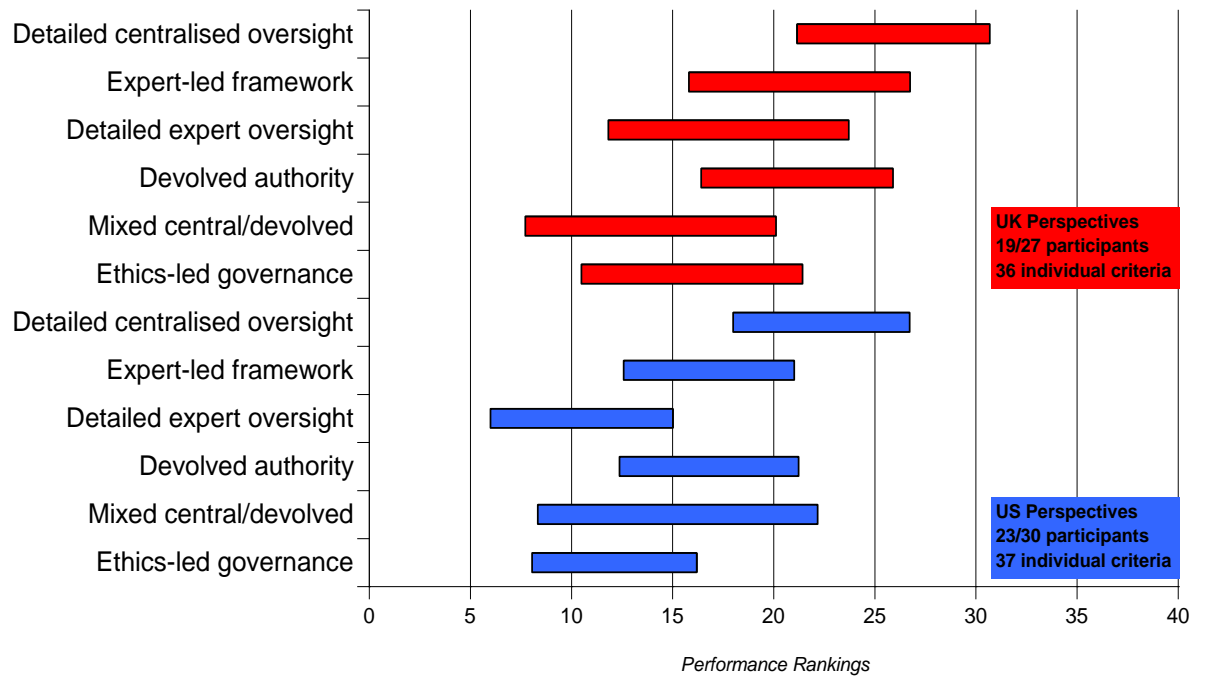
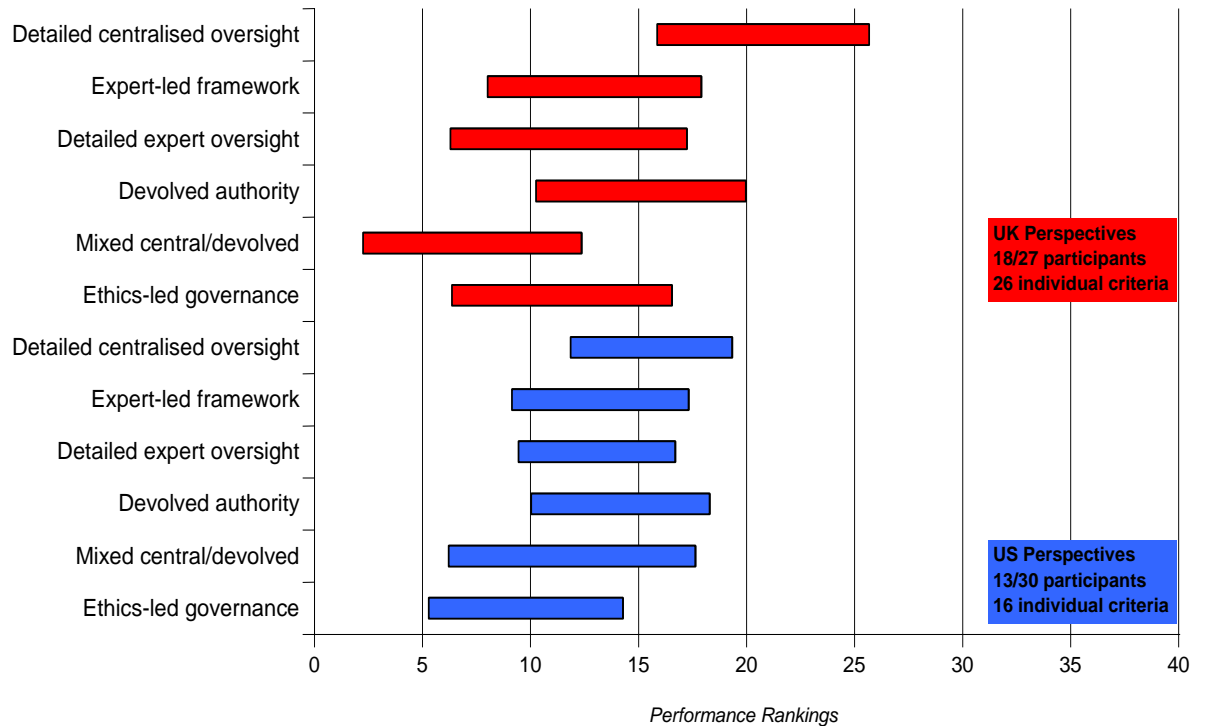


Figure I.6: Rankings for UK and US perspectives under ‘trust (instrumental)’ criteria

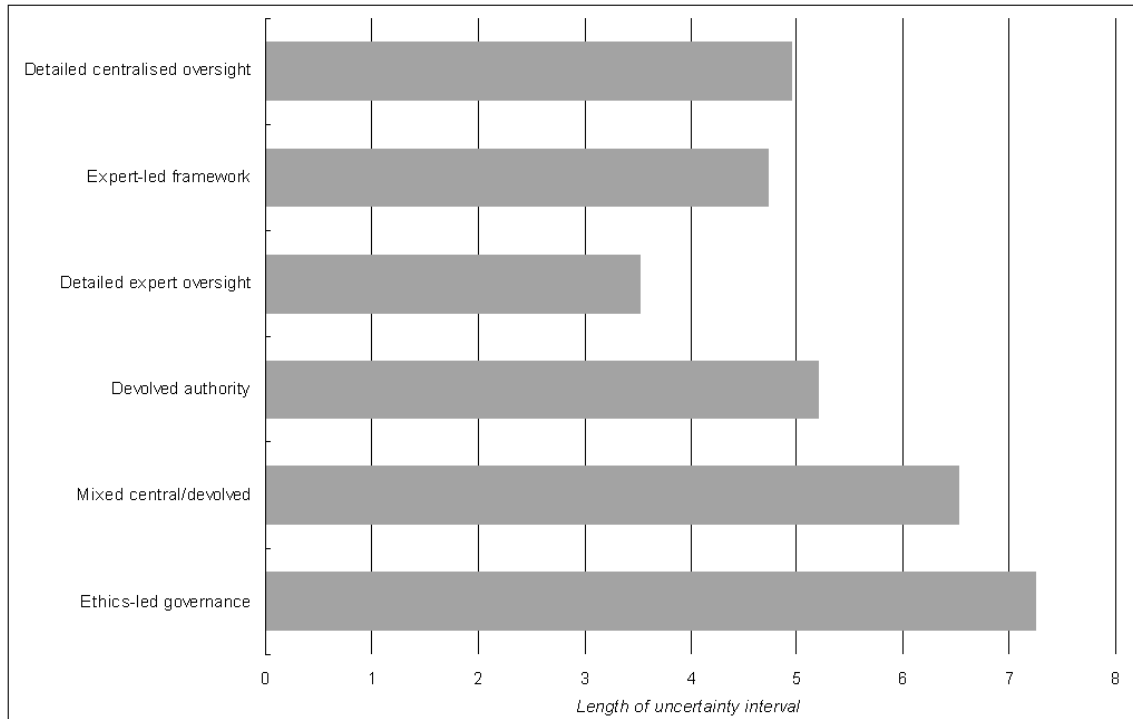
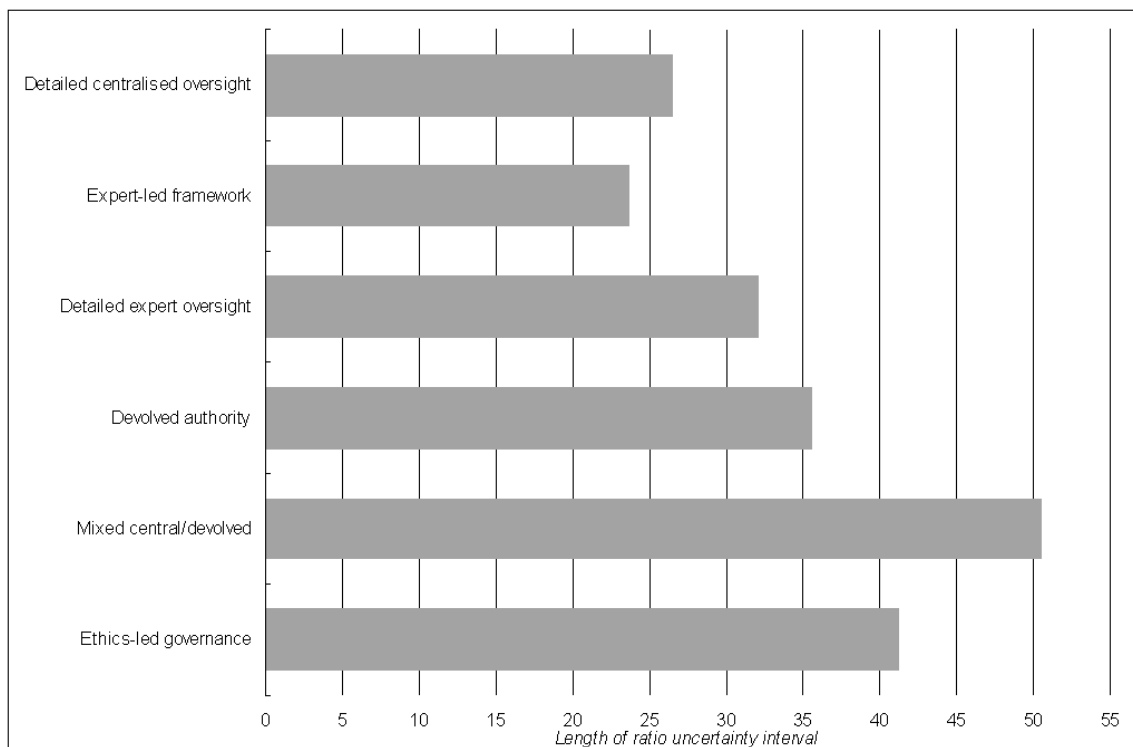


Annex J – Additional Multicriteria Mapping analysis and charts for multiple stakeholder perspectives as presented in Chapter 7

Uncertainty analysis under all performance rankings

In Chapter 7 we call attention to the relative uncertainty and/or ambiguity that is evident in different performance ranking patterns for the stakeholder groups being analysed. While ambiguity can only be determined under individual issues, we can look at expressions of uncertainty at the aggregate level of all option scores under all issues for different groups of stakeholders. Below are a series of figures for each of the stakeholder groups identified in the main text in Chapter 7, Section 7.1.2, where uncertainty seemed to be a significant feature of the ranking patterns. For each perspective, both ‘mean interval uncertainty’ and ‘mean ratio uncertainty’ charts are shown, however for the most part the author relied on mean interval uncertainty as the main measure of uncertainty for a given perspective or issue. Where there are significant differences in the ordinal pattern between mean interval uncertainty and mean ratio uncertainty, this indicates that there was a difference in the way participants expressed uncertainty in relation the absolute value of the scoring ranges. Were this study to be more concerned with *how* uncertainty is expressed, these differences could be probed in further detail. However, the concern here is relative expressions of uncertainty across different groups of participants, and so comparisons are made on the basis of relative expressions under both measures.

Figures J.1 and J.2 below show the mean interval uncertainty and mean ratio uncertainty for laboratory-based scientists. We can see a slight difference in the ordinal pattern between the charts, but generally we find the greatest expression of uncertainty for the mixed central/devolved and ethics-led governance options.

Figure J.1: Mean interval uncertainty for laboratory-based scientists**Figure J.2: Mean ratio uncertainty for laboratory-based scientists**

Figures J.3 and J.4 below show the respective mean interval uncertainty charts for UK and US laboratory-based scientists, while Figures J.5 and J.6 show the mean ratio uncertainty measures for the two groups. We can see that UK scientists express more uncertainty under both measures across all options in comparison to the US scientists, therefore supporting the claim made in Chapter 7 in this regard.

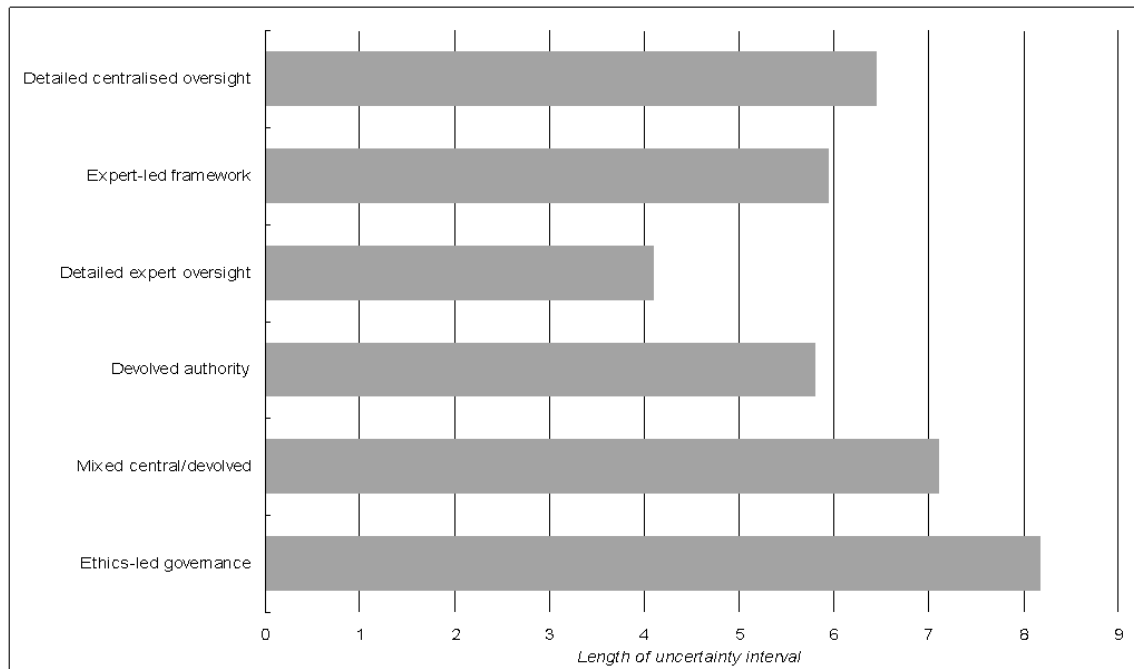
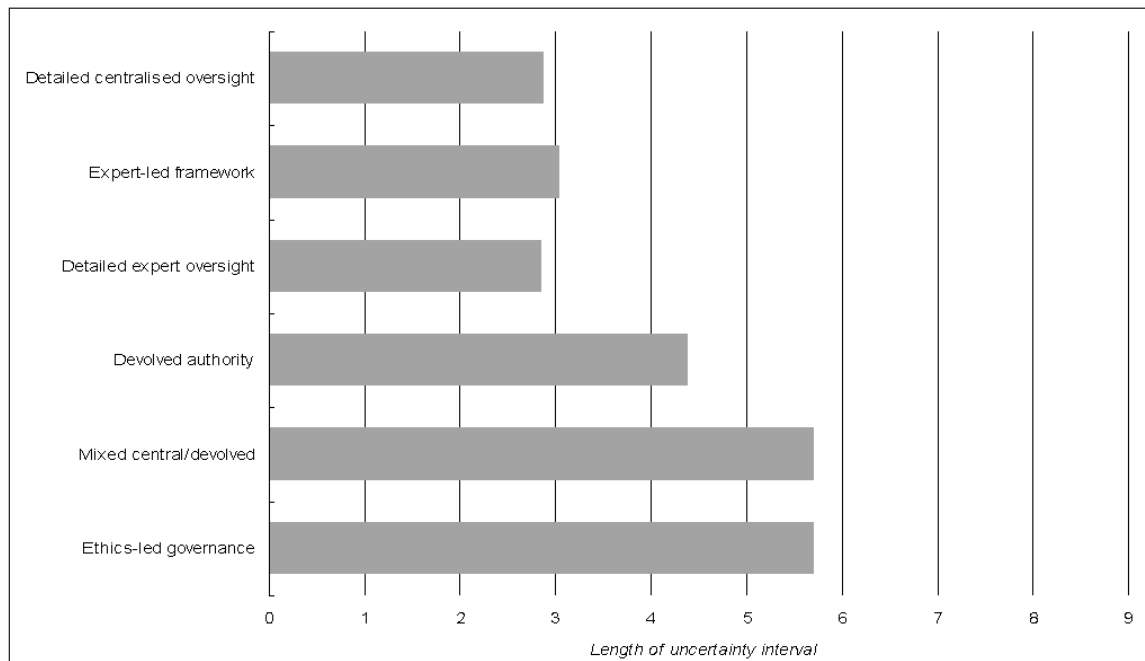
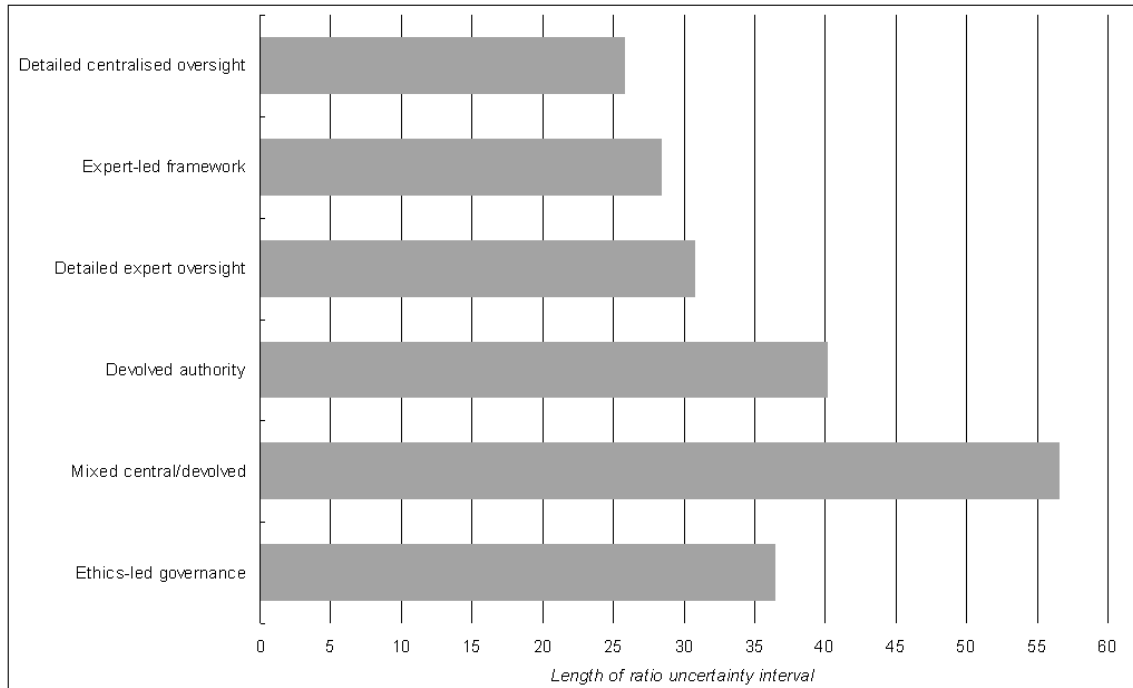
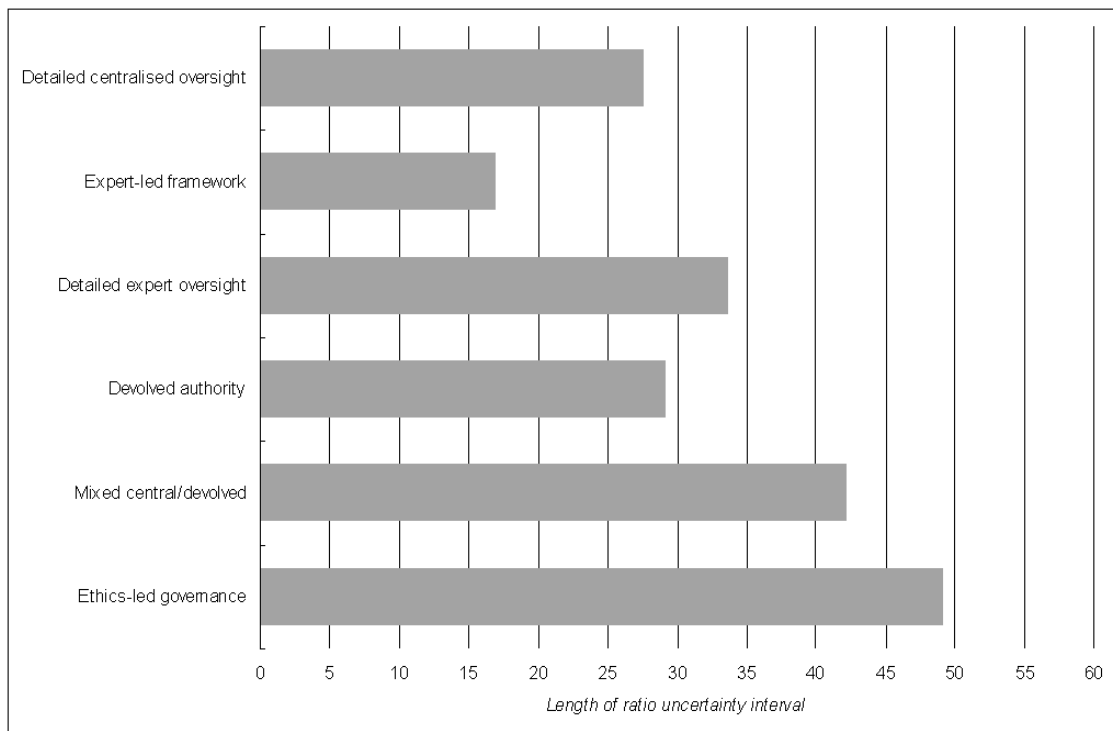
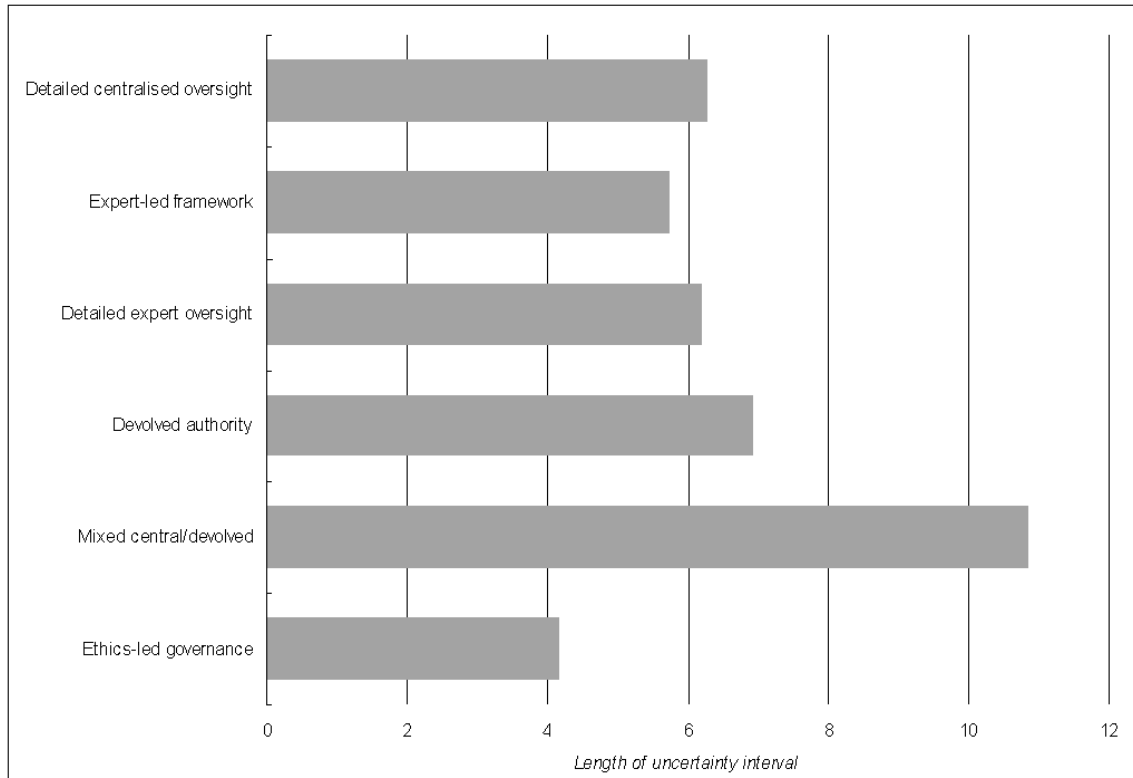
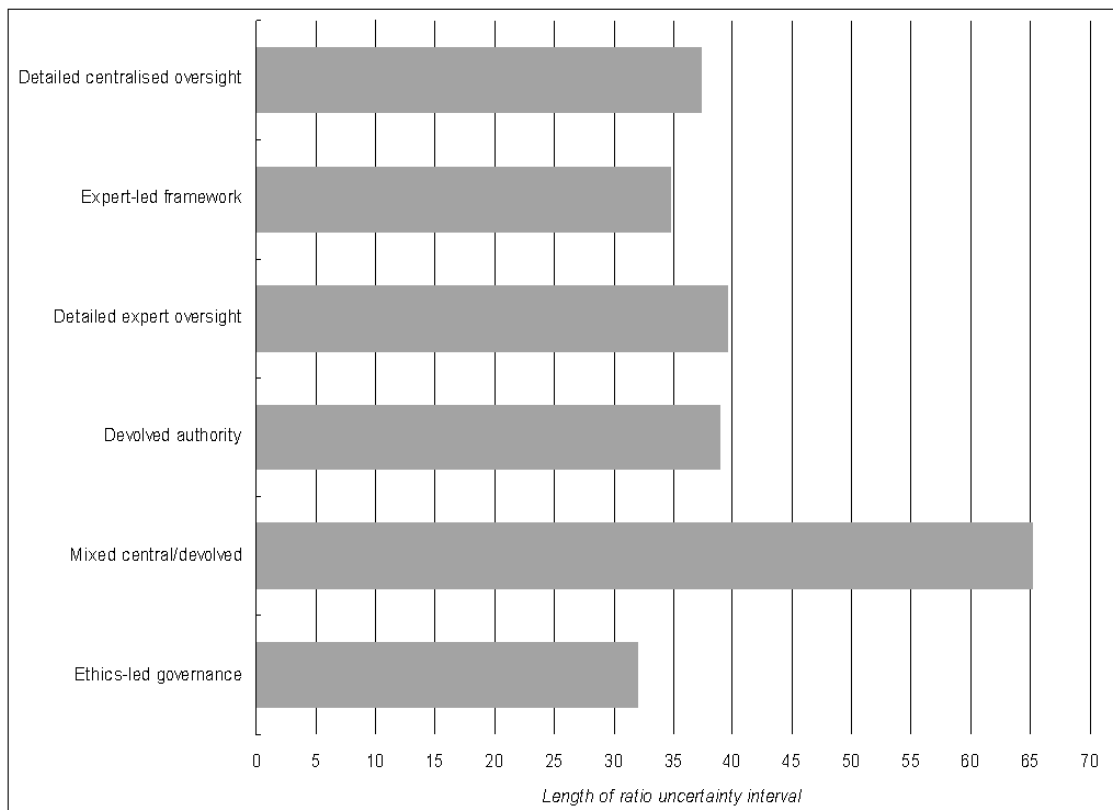
Figure J.3: Mean interval uncertainty for UK laboratory-based scientists**Figure J.4: Mean interval uncertainty for US laboratory-based scientists**

Figure J.5: Mean ratio uncertainty for UK laboratory-based scientists**Figure J.6: Mean ratio uncertainty for US laboratory-based scientists**

Figures J.7 and J.8 below show the uncertainty charts for all advocates interviewed. As pointed out in Chapter 7, we can see clearly how under both measures of uncertainty the mixed central/devolved option has the highest expression of uncertainty.

Figure J.7: Mean interval uncertainty for advocates**Figure J.8: Mean ratio uncertainty for advocates**

Figures J.9 and J.10 show the mean interval uncertainty for UK and US advocates. UK advocates have a more consistent use of uncertainty across all the options,

whereas US advocates express relatively less uncertainty for most of the options, with the notable exception of the mixed central/devolved option (that most analogous to the US governance model). A similar pattern is also seen for mean ratio uncertainty.

Figure J.9: Mean interval uncertainty for UK advocates

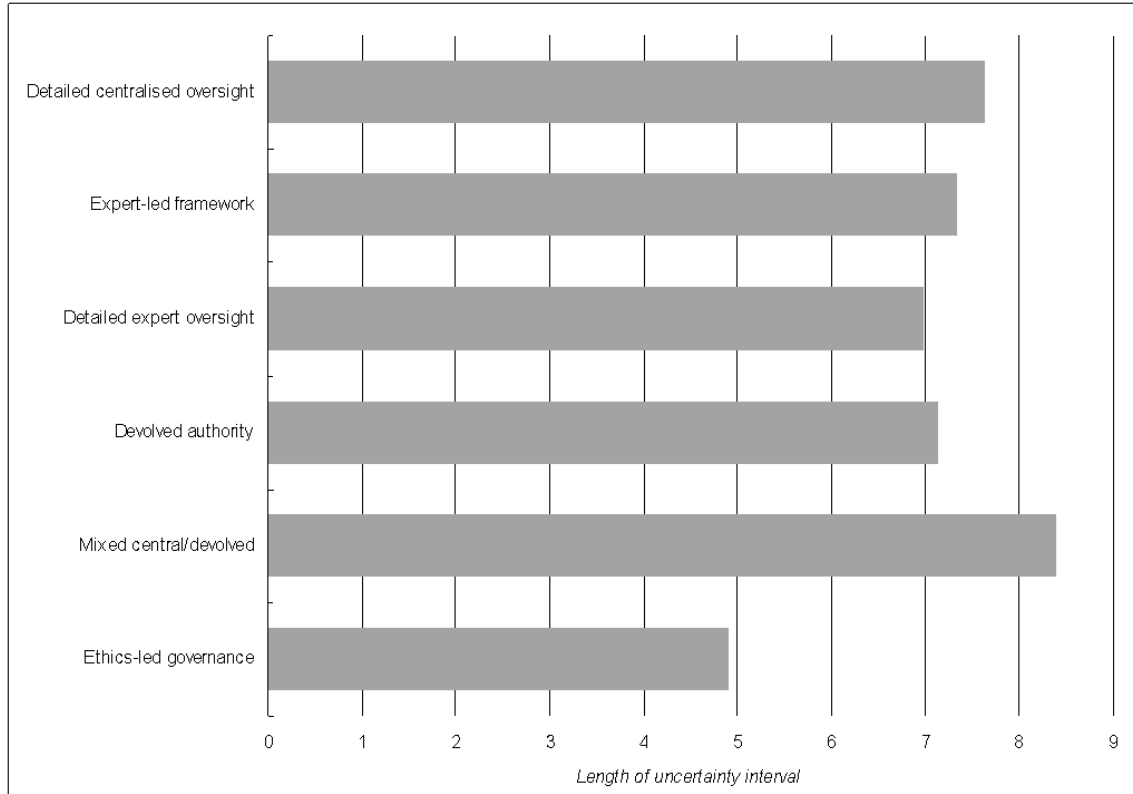


Figure J.10: Mean interval uncertainty for US advocates

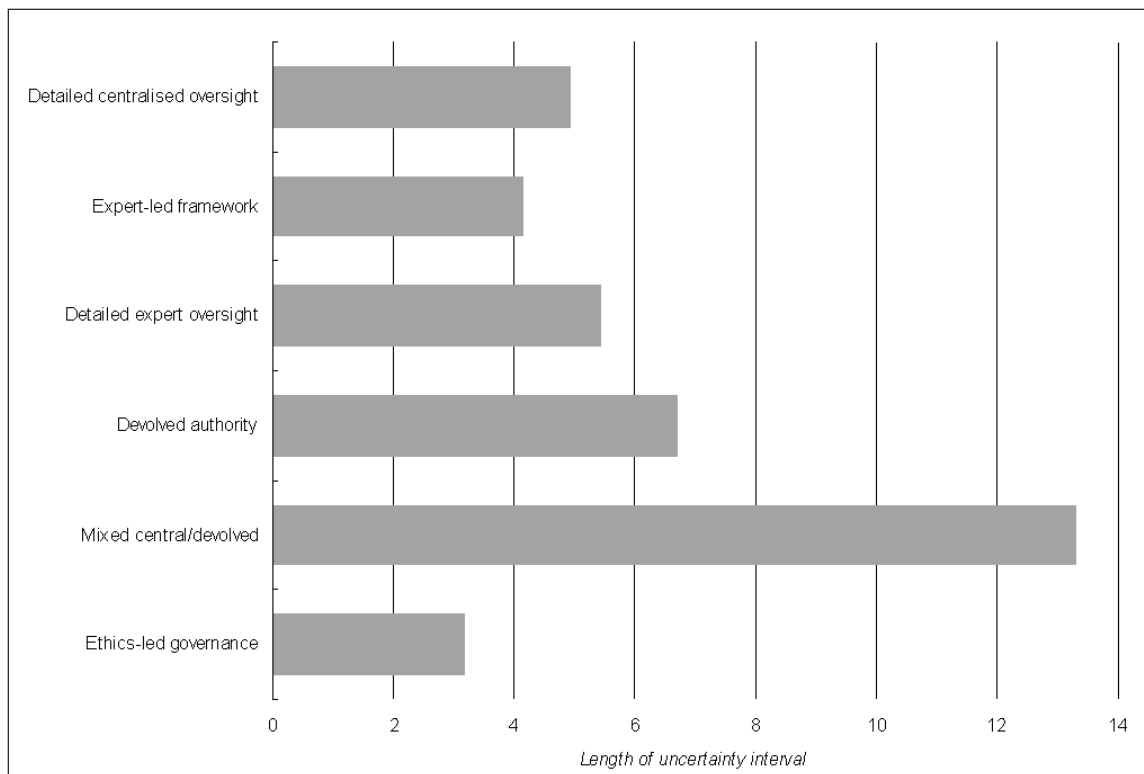
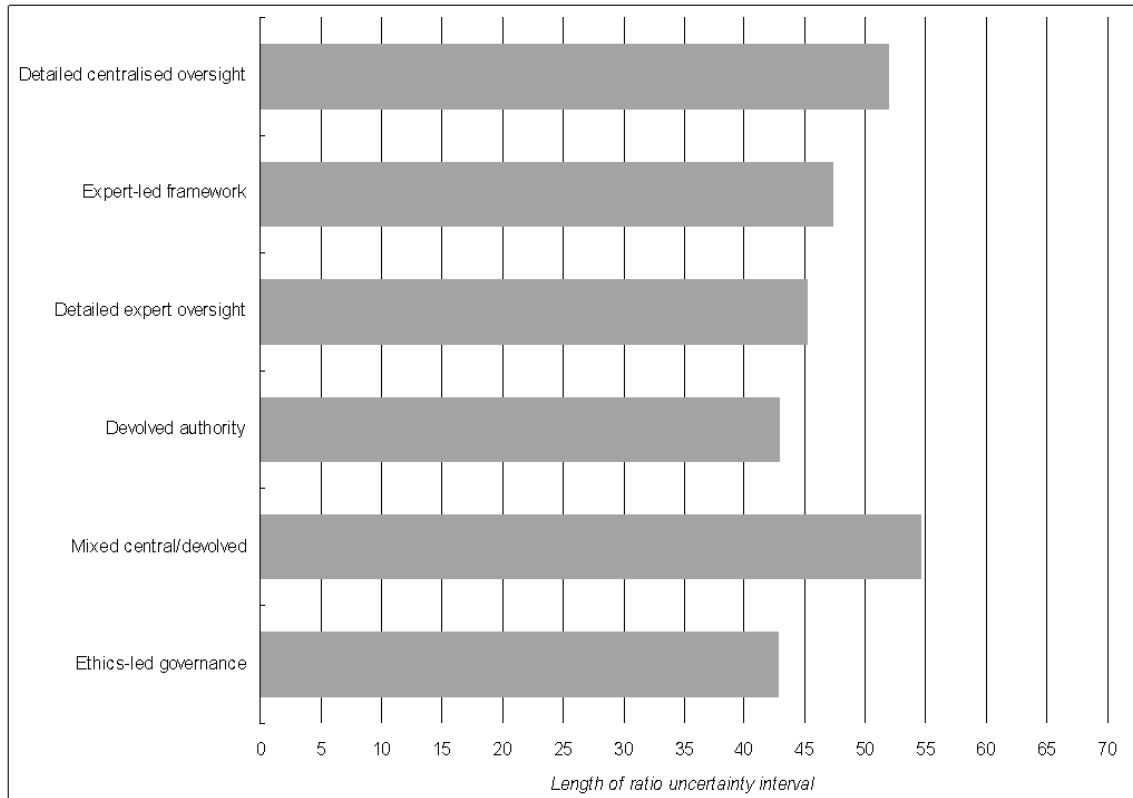
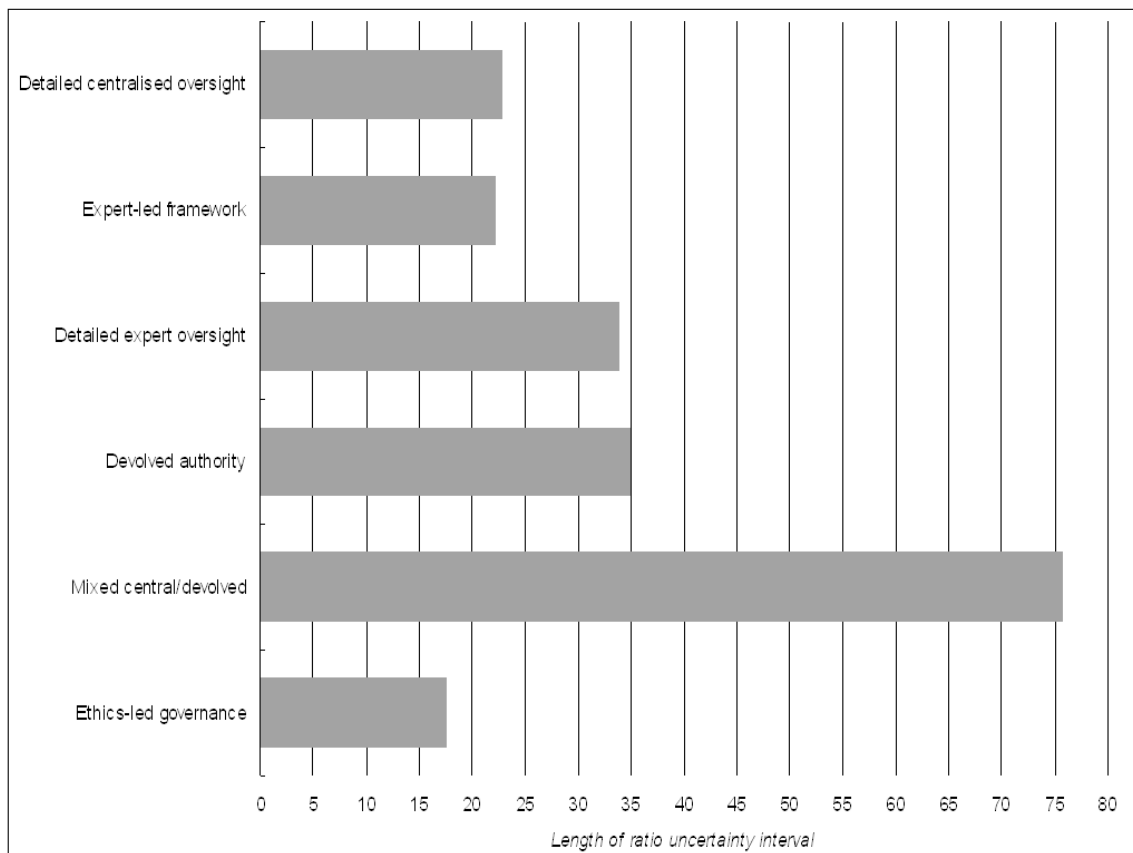


Figure J.11: Mean ratio uncertainty for UK advocates**Figure J.12: Mean ratio uncertainty for US advocates**

Mean weightings for criteria discussed in Chapter 7

Table J.1: Summary table for criteria discussed in Chapter 7

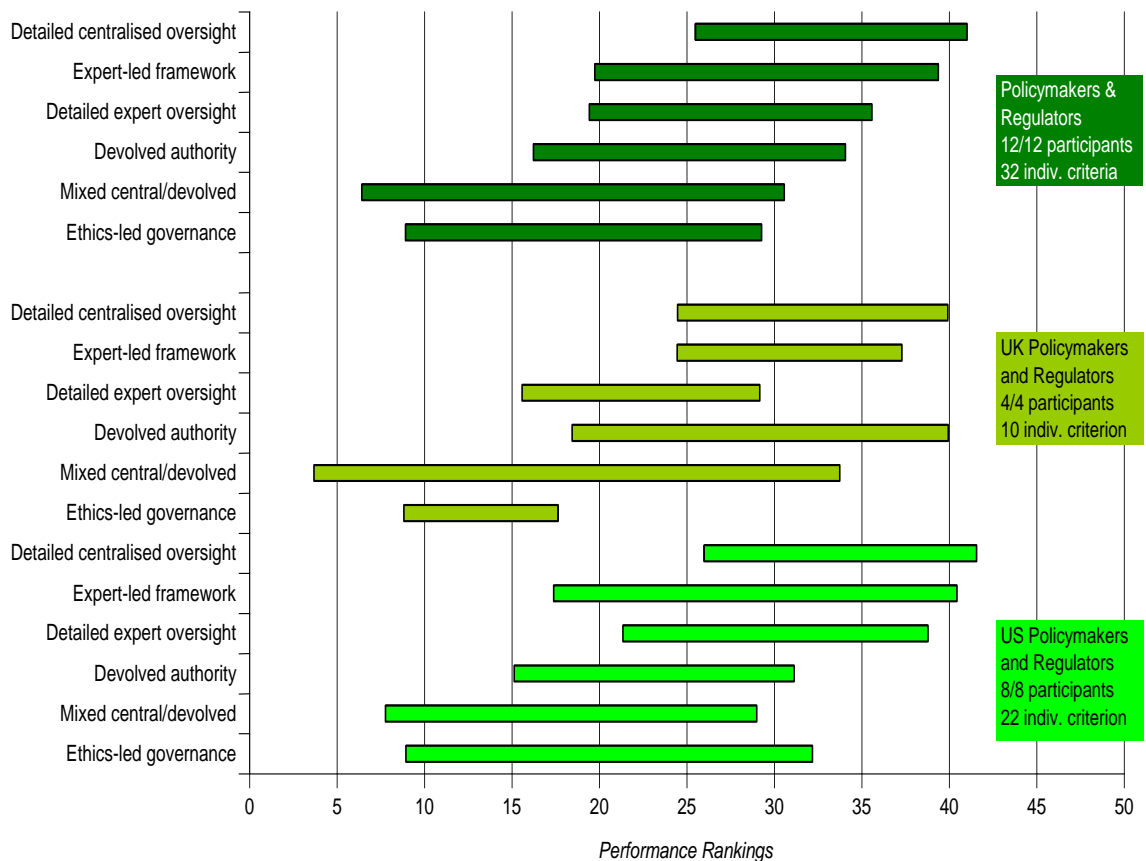
Criteria Type	Advocates	Bioethicists	Industry & Professional	Policy-makers & Regulators	Scientists (Labs)
Advances the science	10/12 participants 22 criteria; Mean weighting 31%	8/9 participants 15 criteria; Mean weighting 30%	12/12 participants 30 criteria; Mean weighting 52%	12/12 participants 32 criteria; Mean weighting 48%	11/12 participants 23 criteria; Mean weighting 38%
Qualities of deliberative activities	10/12 participants 23 criteria; Mean weighting 40%	9 participants 16 criteria; Mean weighting 32%	11/12 participants 19 criteria; Mean weighting 29%	9/12 participants 17 criteria; Mean weighting 27%	12/12 participants 24 criteria; Mean weighting 34%
Role of the public	8/12 participants 10 criteria; Mean weighting 20%	8/9 participants 11 criteria; Mean weighting 20%	8/12 participants 11 criteria; Mean weighting 14%	8/12 participants 13 criteria; Mean weighting 20%	9/12 participants 13 criteria; Mean weighting 18%
Nature of expertise	5/12 participants 12 criteria; Mean weighting 18%	5 participants 5 criteria; Mean weighting 12%	7/12 participants 8 criteria; Mean weighting 15%	4/12 participants 4 criteria; Mean weighting 7%	8/12 participants 11 criteria; Mean weighting 17%

Additional analysis under ‘advances the science’ criteria

Policymakers and regulators

The figure below shows the option performance rankings for UK and US policy-makers and regulators which are referred to in Chapter 7, Section 7.2.2.

Figure J.13: Performance rankings for UK and US policymakers and regulators under the ‘advancing the science’ issue



The performance rankings for the UK policymakers and regulators show a preference for two highly centralised options: detailed centralised oversight and devolved authority. However, there is more uncertainty and ambiguity for the devolved authority option and we also see a high level of uncertainty and ambiguity within the mixed central/devolved option. This pattern suggests that the UK-based perspective may favour options with some degree of centralised oversight and regulation. The rankings for US policymakers and regulators seem to reflect the desire to support good science and put structures in place which are flexible, effective and foster consistency in oversight. The options that are most favoured all have at least one feature of centralisation, thus ensuring consistency and harmonisation of policy. Where there is decentralisation, such as seen in the expert-led framework with its regional oversight bodies, there is also a high expression of uncertainty and ambiguity.

Uncertainty and ambiguity expressed by laboratory-based scientists

The series of figures below show the uncertainty and ambiguity for different groups of laboratory scientists under ‘advances the science’ criteria. They support the point made in Chapter 7, Section 7.2.2, about uncertainty and ambiguity within this stakeholder group. UK scientists, in particular, are both more uncertain and more ambiguous (in relation to each other) in assessing the options than US scientists. This point is seen in comparing Figures J.14 through J.17 below.

Figure J.14: Mean interval uncertainty for UK laboratory scientists under ‘advances the science’ criteria

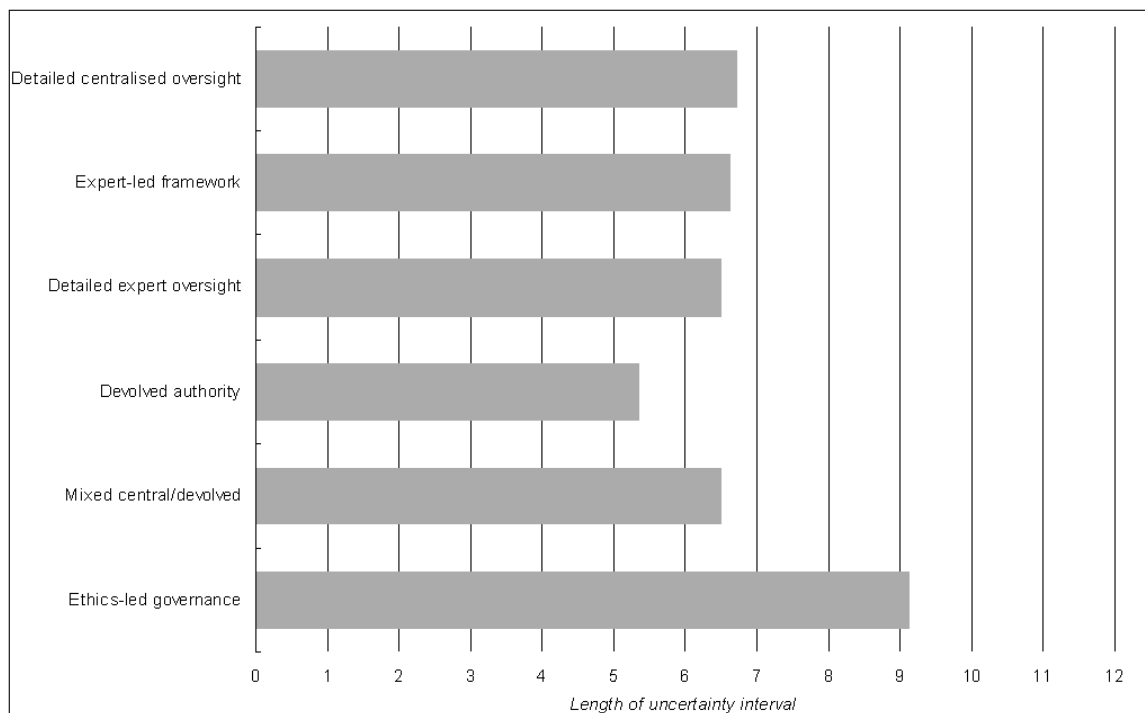


Figure J.15: Mean ambiguity for UK laboratory scientists under ‘advances the science’ criteria

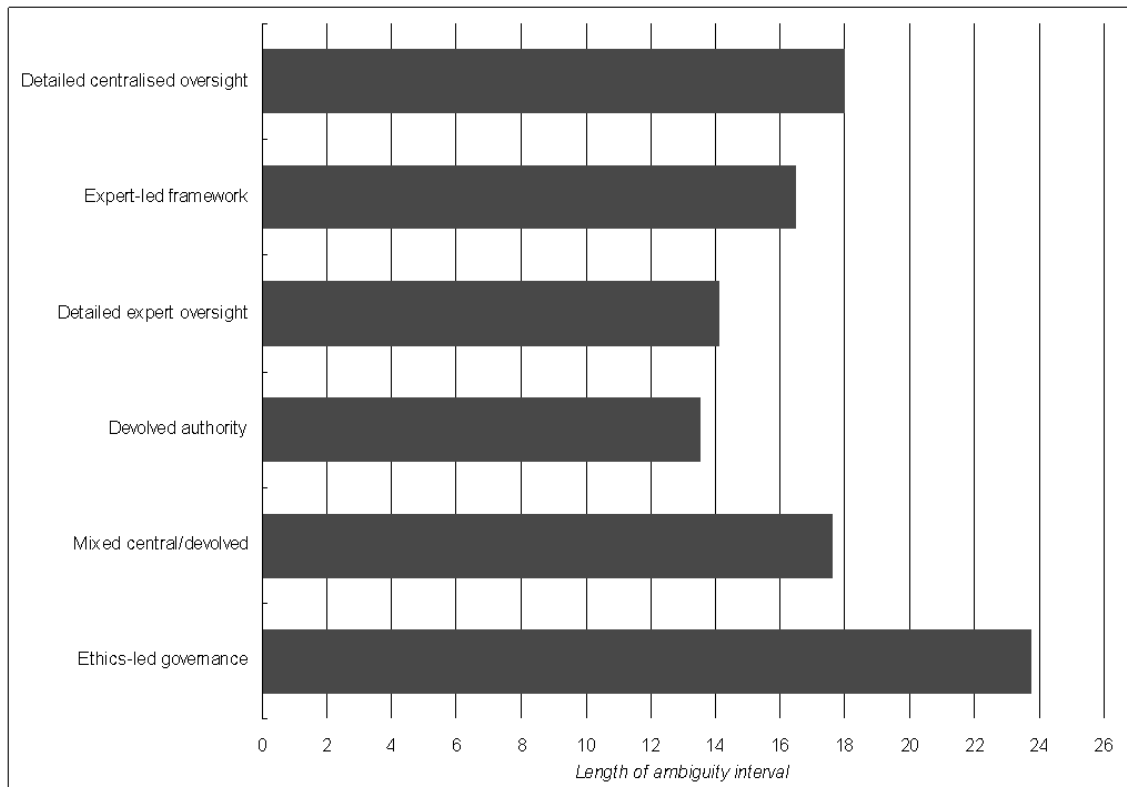


Figure J.16: Mean interval uncertainty for US laboratory scientists under ‘advances the science’ criteria

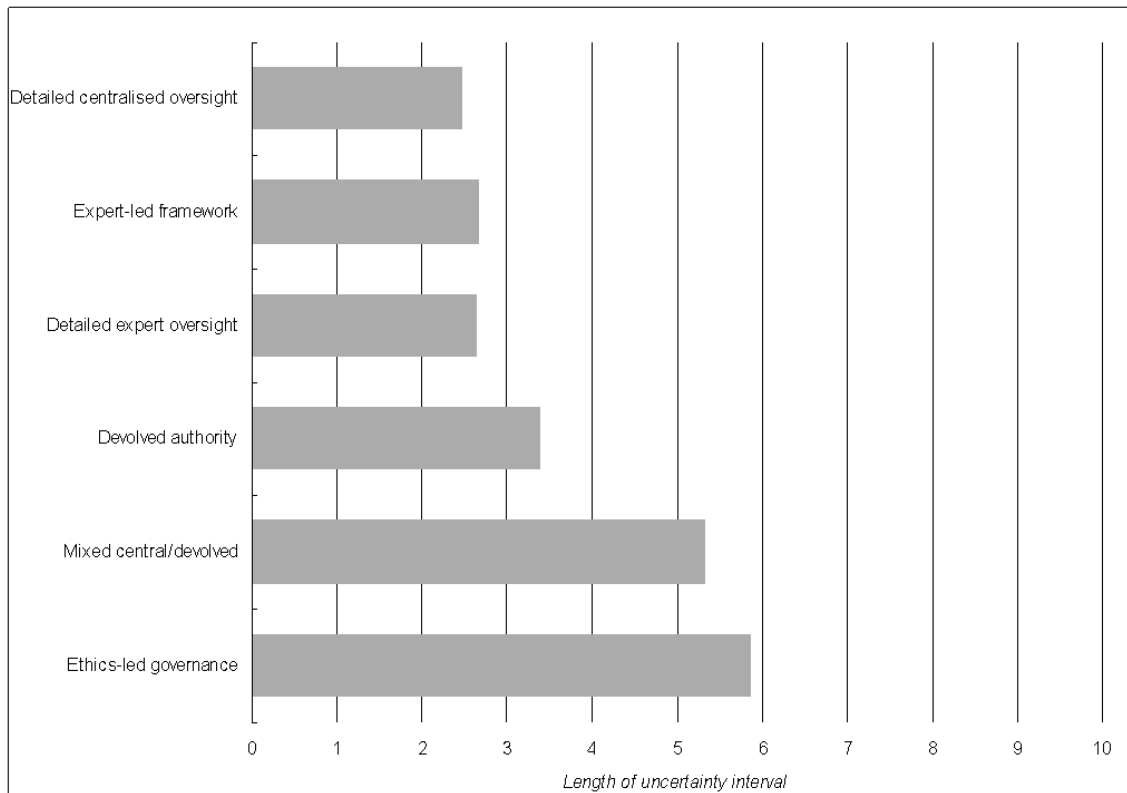
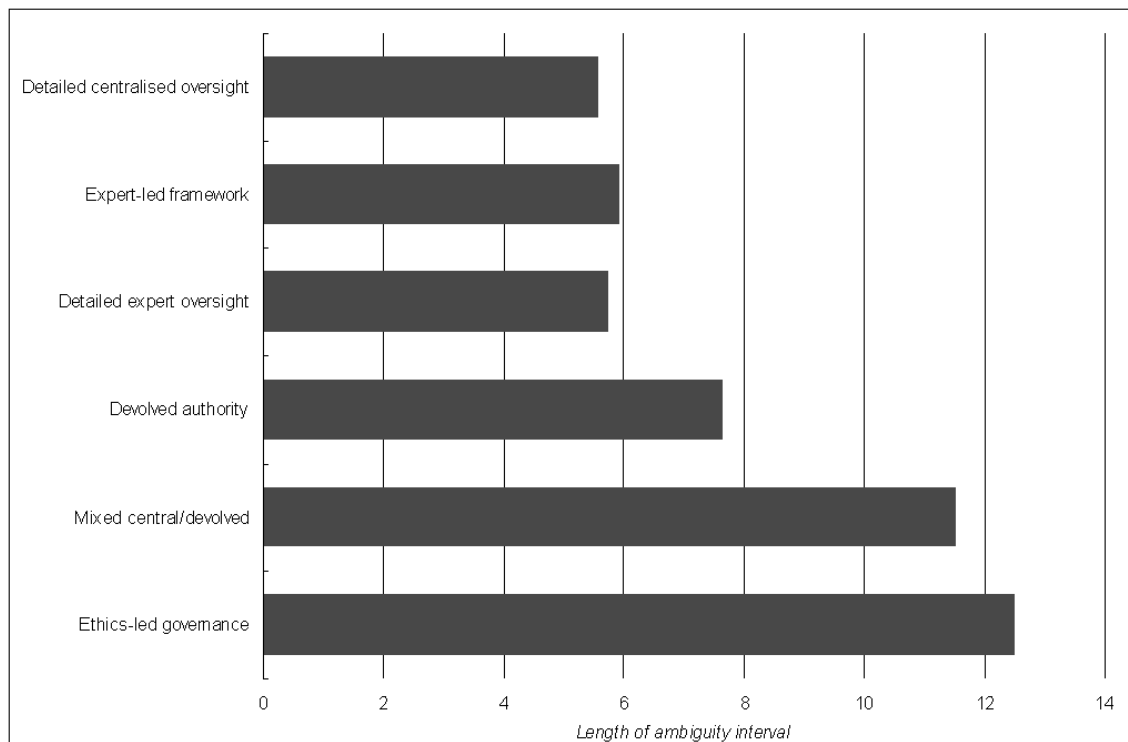
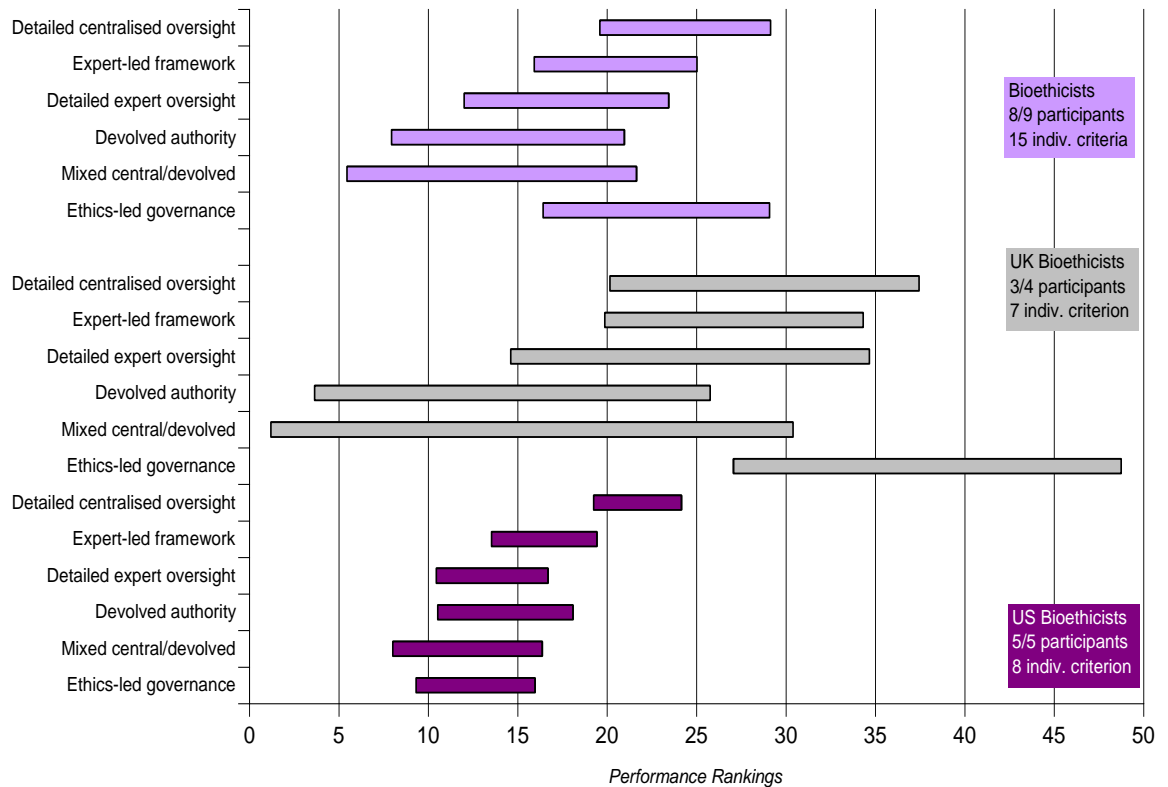


Figure J.17: Mean ambiguity for US laboratory scientists under ‘advances the science’ criteria



Bioethicists

The analysis of the issue ‘advancing the science’ for bioethicists is presented in Chapter 7 in Section 7.2.2. The performance ranking charts for UK and US bioethicists is shown in Figure J.18 below.

Figure J.18: Rankings for bioethicists under ‘advancing the science’ criteria

We can see from this figure that there are real differences in the ordinal pattern of performance rankings of UK and US bioethicists. However, the analysis in Chapter 7 showed that there was little difference in the qualitative analysis of the criteria which composed the issue. This seems to support the conclusion that despite the similar framing of the criteria within the issue, their evaluations of the options themselves vary. In other words, though the framing is similar, the way that the options are interpreted is different. The two figures below compare the uncertainty and ambiguity for this stakeholder group under ‘advances the science’ criteria and we do see greater ambiguity evident than uncertainty, although the overall patterns are the same, indicating that where there was uncertainty, there was also disagreement over option performance, and these patterns varied consistently across the options.

Figure J.19: Mean interval uncertainty for bioethicists under ‘advances the science’ criteria

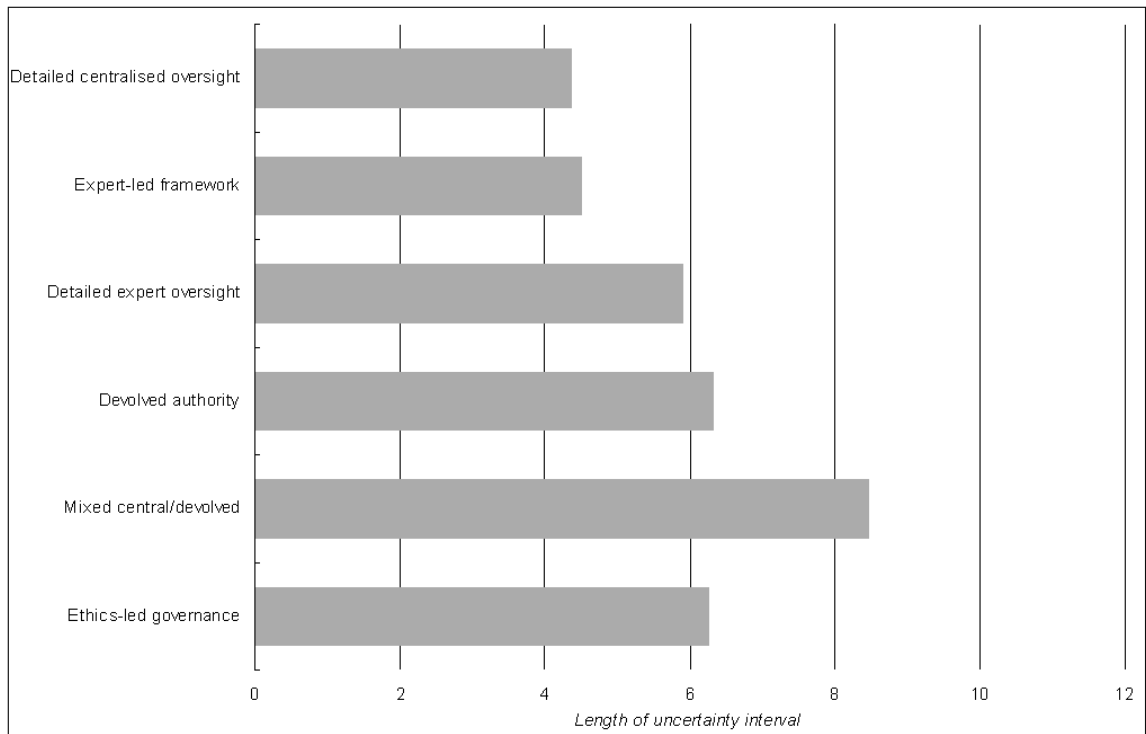
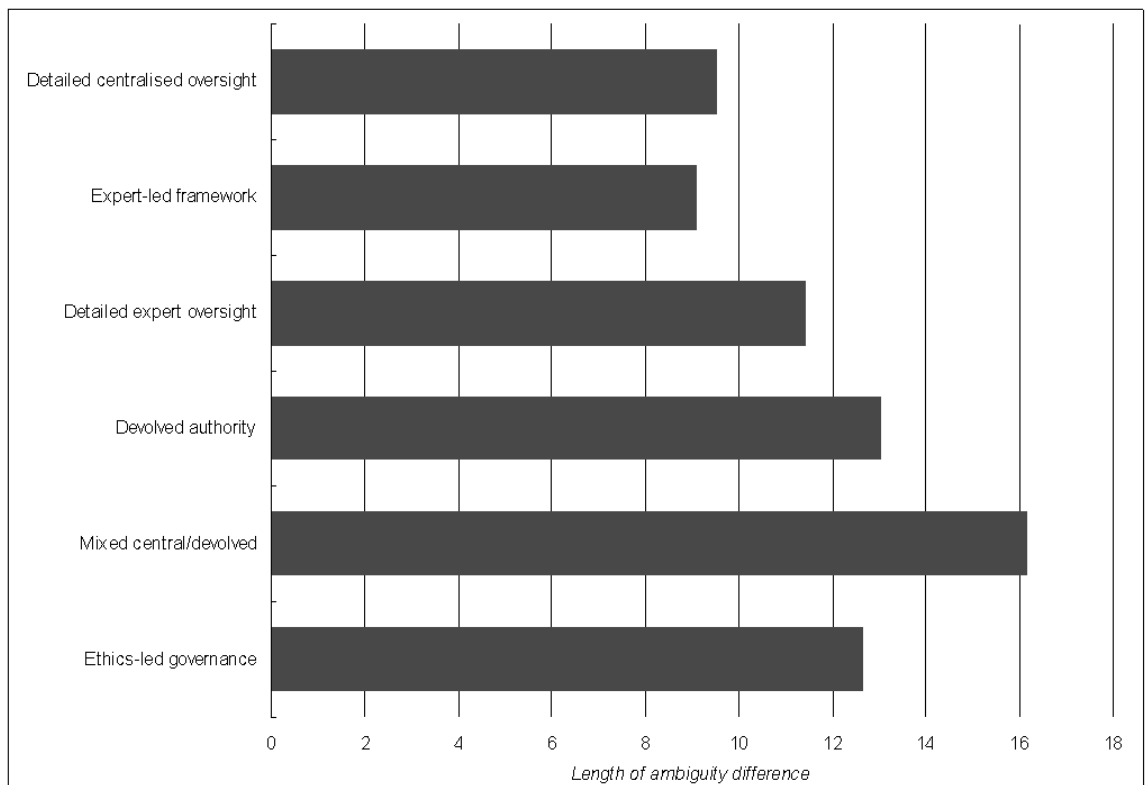


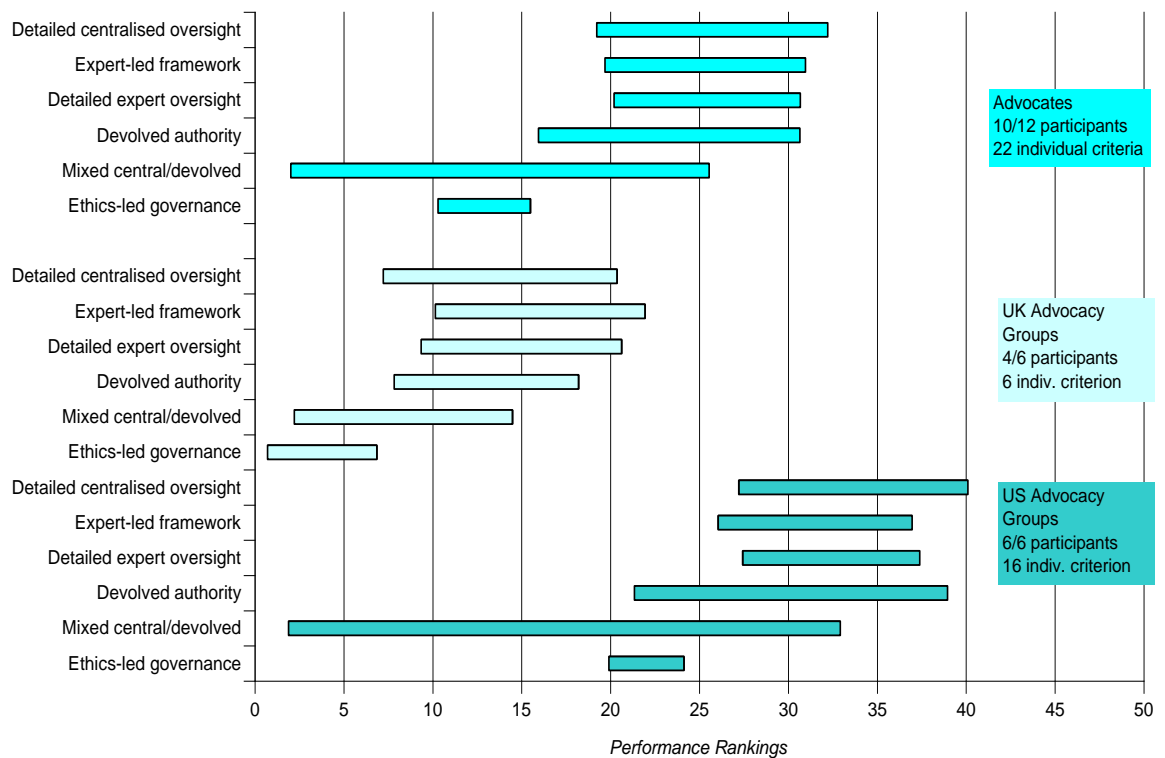
Figure J.20: Mean ambiguity for bioethicists under ‘advances the science’ criteria



Advocates

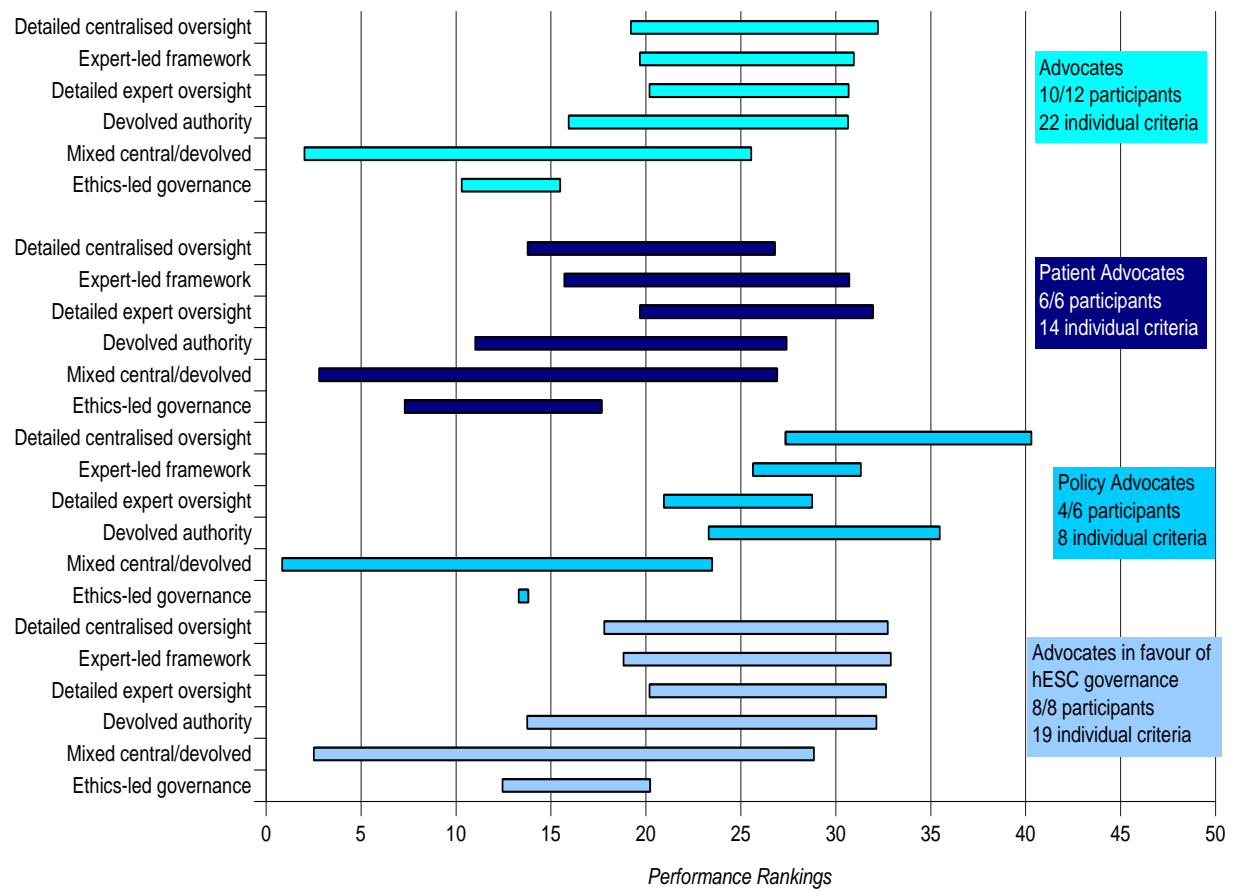
In Chapter 7, different types of advocacy groups were analysed. UK and US-based advocacy groups have similar performance rankings to the ordinal pattern at the overall group level and are shown below.

Figure J.21: Rankings of US and UK advocacy groups under the issue ‘advancing the science’



However, there are differences based upon the type of advocate the participant was – a patient advocate or a policy advocate – as shown in Figure J.24 below. Rankings for participants who advocated for changes to the hESC governance framework because they are opposed to it are not shown because only 2 criteria were defined.

Figure J.22: Rankings of multiple types of Advocates under the issue 'advancing the science'



First, we can see that under patient advocate perspectives for this issue the ‘detailed expert oversight’ option has the highest performance ranking under optimistic scores, followed very closely by the expert-led framework (a difference of approximately 2 base points). Conversely, under policy advocate perspectives the detailed centralised oversight option has the higher performance ranking under optimistic scores, followed by the devolved authority option (a difference of approximately 5 base points). Under both options the ethics-led governance option¹⁶⁶ and the mixed central/devolved option were two of the worst performing options overall.

A few implications of these different ordinal ranking patterns are highlighted here. First, the high performance ranking of the detailed expert oversight option under patient advocate perspectives is intriguing because this option has prescriptive regulations and centralised oversight. Previous perspectives have found these features to

¹⁶⁶ The extremely small expression of uncertainty seen for the ethics-led option under policy advocate perspectives is explained by the fact that only 3 of the 6 participants evaluated this option due to its inclusion as a ‘core’ MCM option after an initial set of interviews had already been conducted (see explanation and justification for this as given in Chapter 4). The three participants who did evaluate this option, coincidentally, all used very small ranges of uncertainty in their evaluation of the option.

translate into a rigid and inflexible option, some of the opposite characteristics from what advocates expressed as important components of facilitating a beneficial, therapeutic hESC trajectory. However, the option also relies on expert-based decision-making for research approval. As we point out in Chapter 7, many patient advocates thought this could facilitate moving the science forward, faster.

Second, as both types of advocates framed the hESC trajectory in terms of social and public benefits, it is not entirely unexpected that each group favoured options that had centralised oversight and detailed regulations. This, it is believed, ensures ‘consistency’ in the science and helps to direct science towards particularly desired goals. An explanation for the difference in the type of centralised option each type of advocate preferred lies in types of public benefit each group would like to see. Thus, policy advocates expressed a preference for the detailed centralised oversight option as opposed to the detailed expert oversight option because it had a greater role for public inputs, which would prevent the science from being controlled by one group of ‘expert’ interests. Though both groups of advocates had similar motivations for why they favour different options, there are clear differences in the way these motivations were revealed in the option assessments.

Industry and professional executives

The charts below show the uncertainty and ambiguity charts for various groupings of stakeholders within the group ‘industry and professional executives’. They show that industry executives express both greater uncertainty and ambiguity in evaluating the options in comparison with participants who are from professional bodies. As pointed out in Chapter 7, this could explain the different ordinal ranking patterns observed between the two groups.

Figure J.23: Mean interval uncertainty for industry executives under ‘advances the science’ criteria

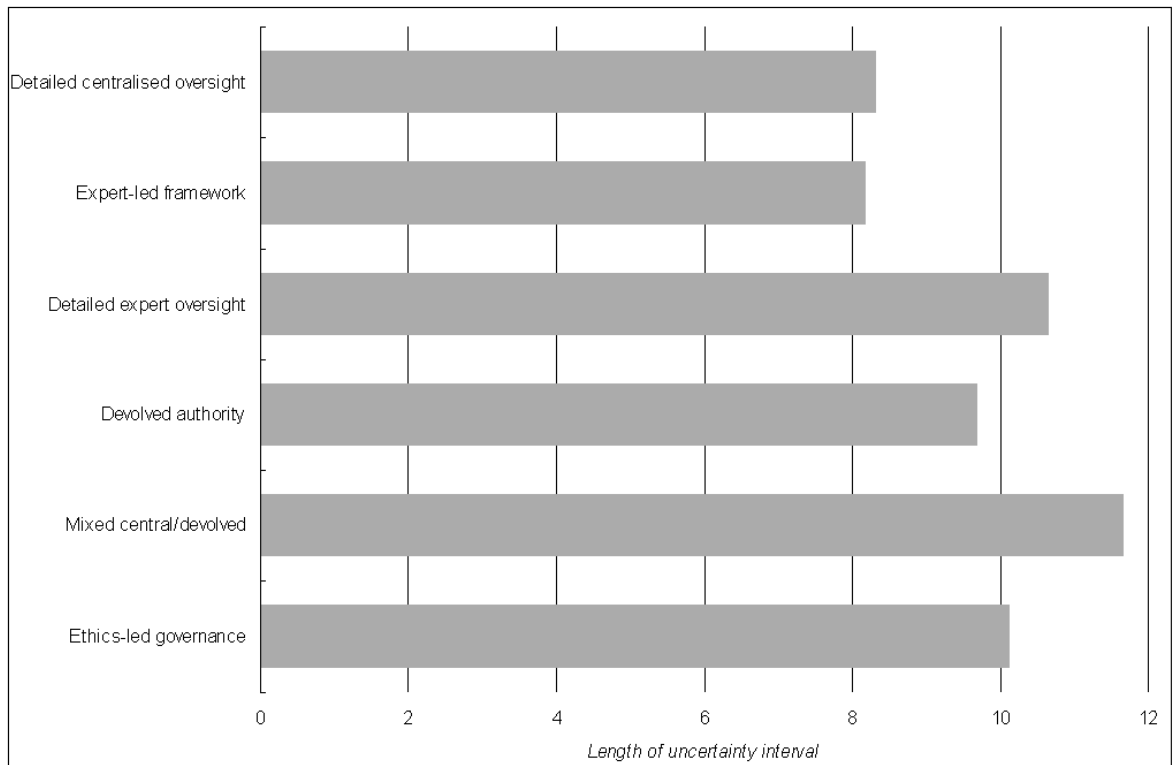


Figure J.24: Mean ambiguity for industry executives under ‘advances the science’ criteria

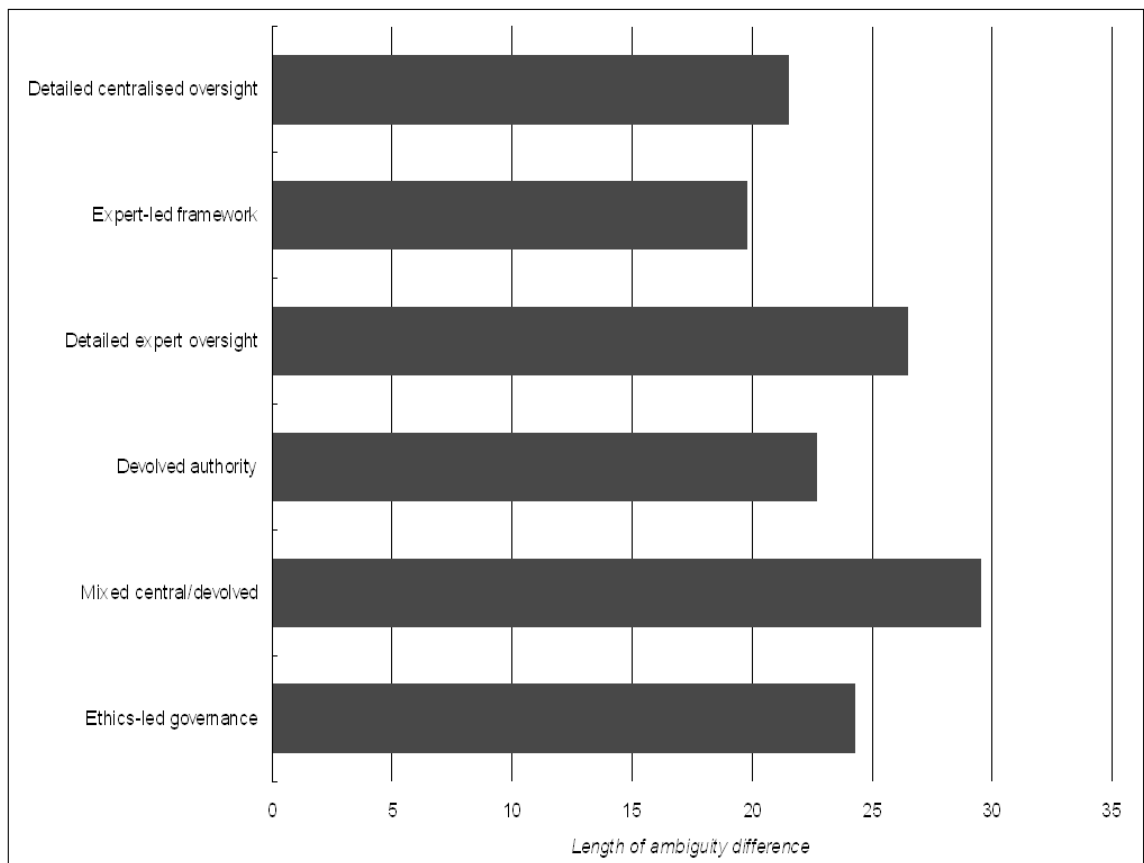


Figure J.25: Mean interval uncertainty for professional body representatives under ‘advances the science’ criteria

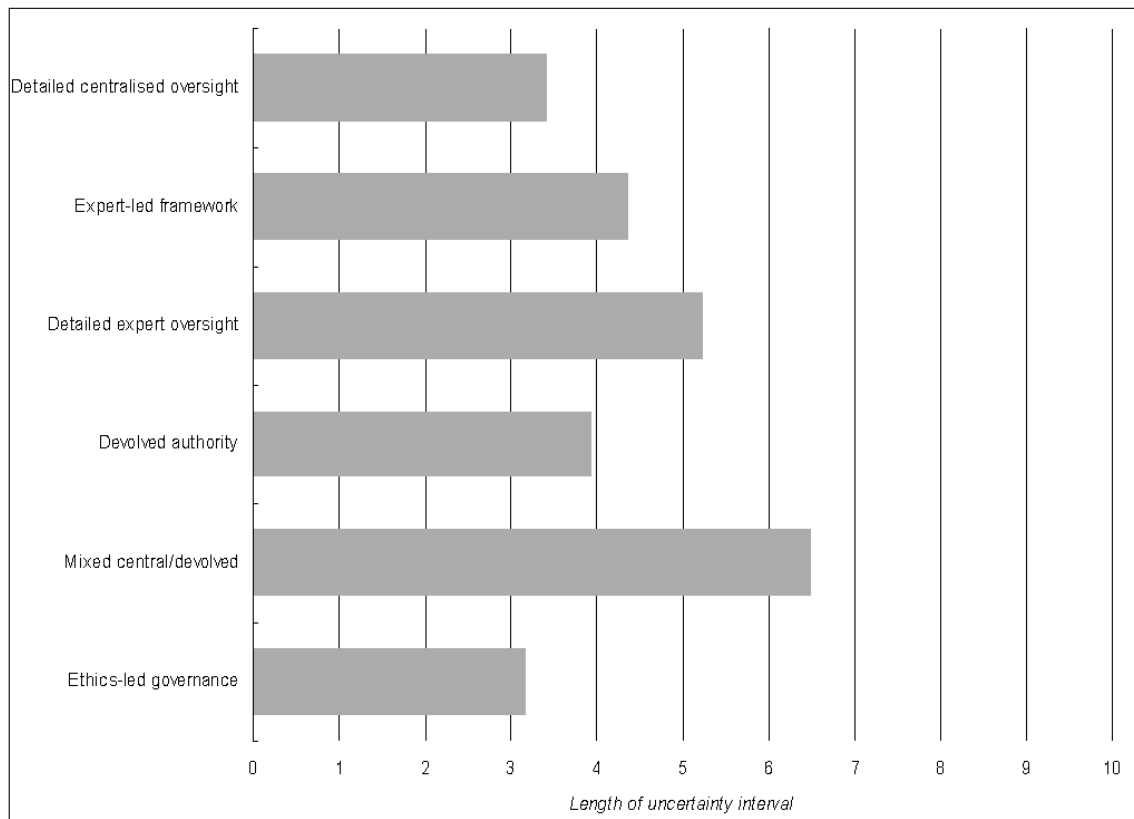
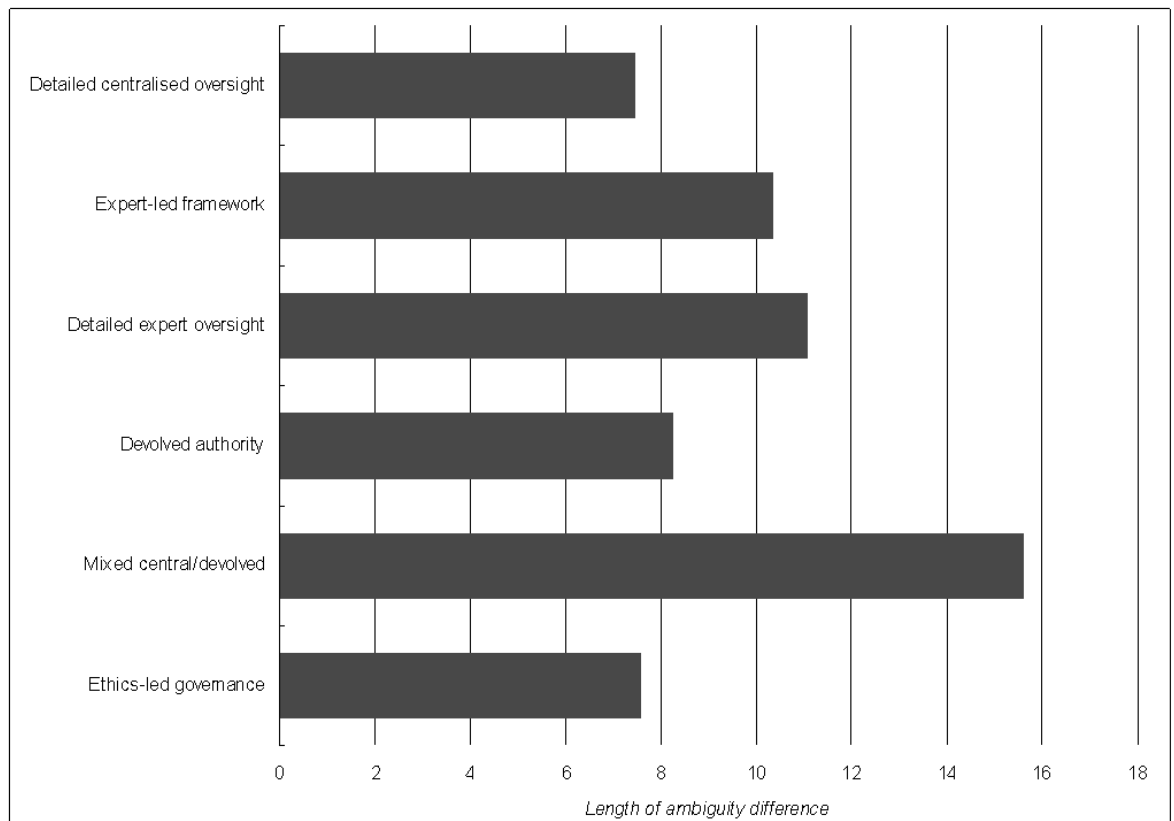


Figure J.26: Mean ambiguity for professional body representatives under ‘advances the science’ criteria

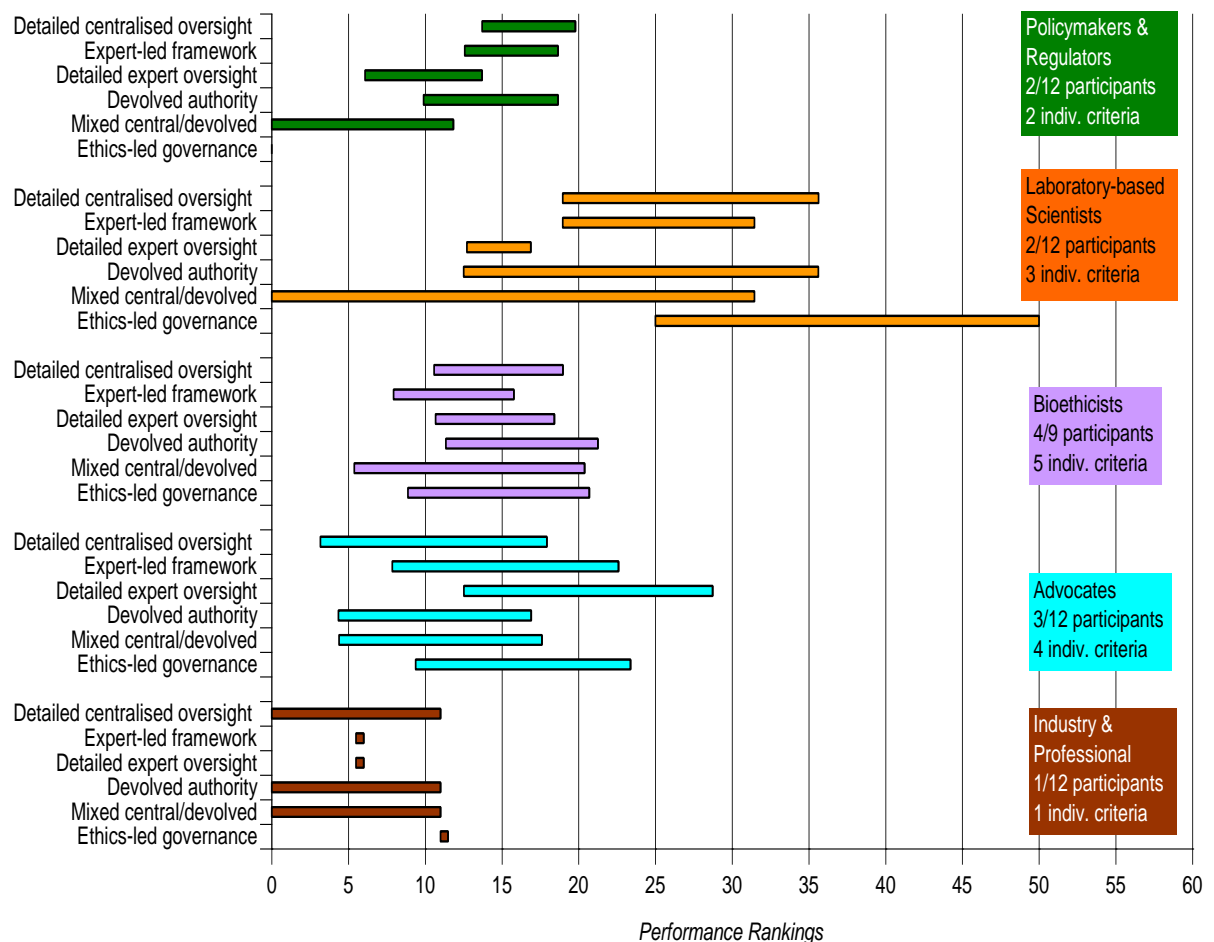


Annex K – Additional Multicriteria Mapping analysis and ranking charts for points made in Chapter 8

Rankings for normative, substantive and instrumental criteria

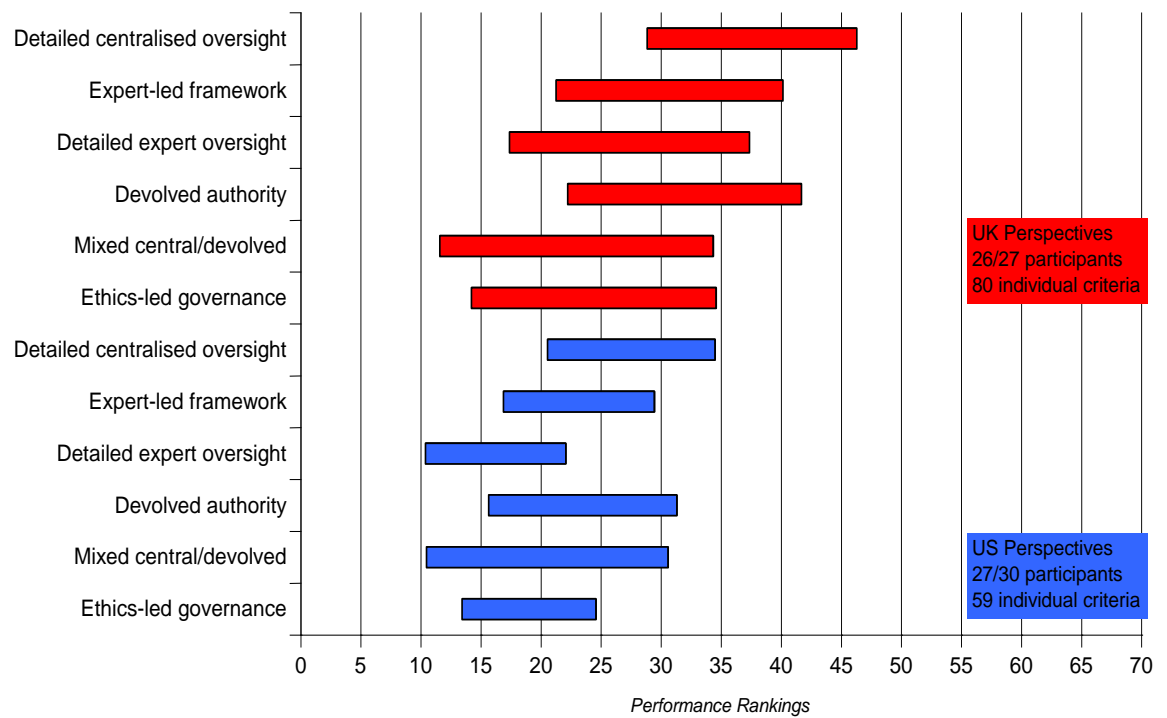
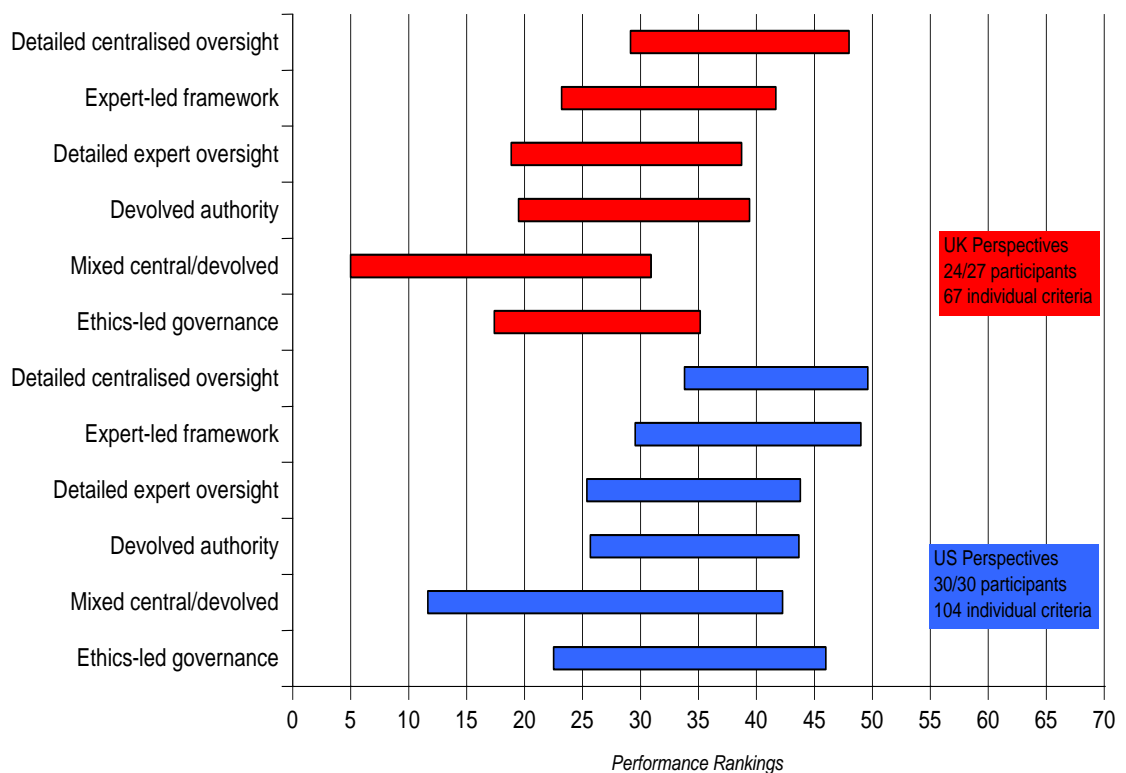
In Chapter 8 the normative, instrumental and substantive imperatives which were found to be present as underlying rationales affecting option appraisal were probed in relation to the MCM empirical findings. Figure K.1 shows the rankings for stakeholder perspectives under substantive criteria, the only chart not shown in the main text in Chapter 8 in relation to these types of criteria.

Figure K.1: Rankings for stakeholder perspectives under substantive criteria



Rankings for process and outcome criteria

The two figures below show the performance rankings for UK and US perspectives for the two issues ‘process-based’ and ‘outcome-based’:

Figure K.2: Rankings of UK and US perspectives on process-based criteria**Figure K.3: Rankings of UK and US perspectives for outcome-based criteria**

The figures below show the rankings for outcome- and process-based criteria across the five main stakeholder groups.

Figure K.4: Performance rankings of initial stakeholder perspectives under process-based issues

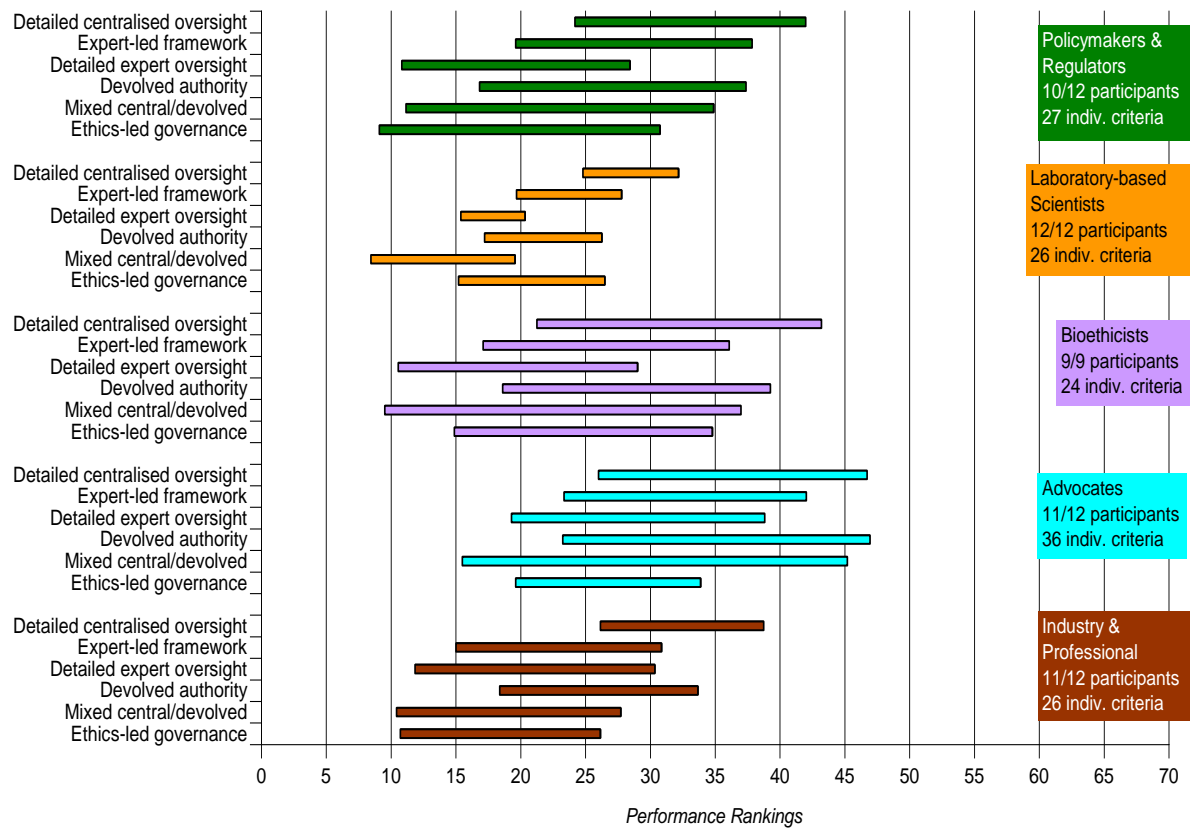
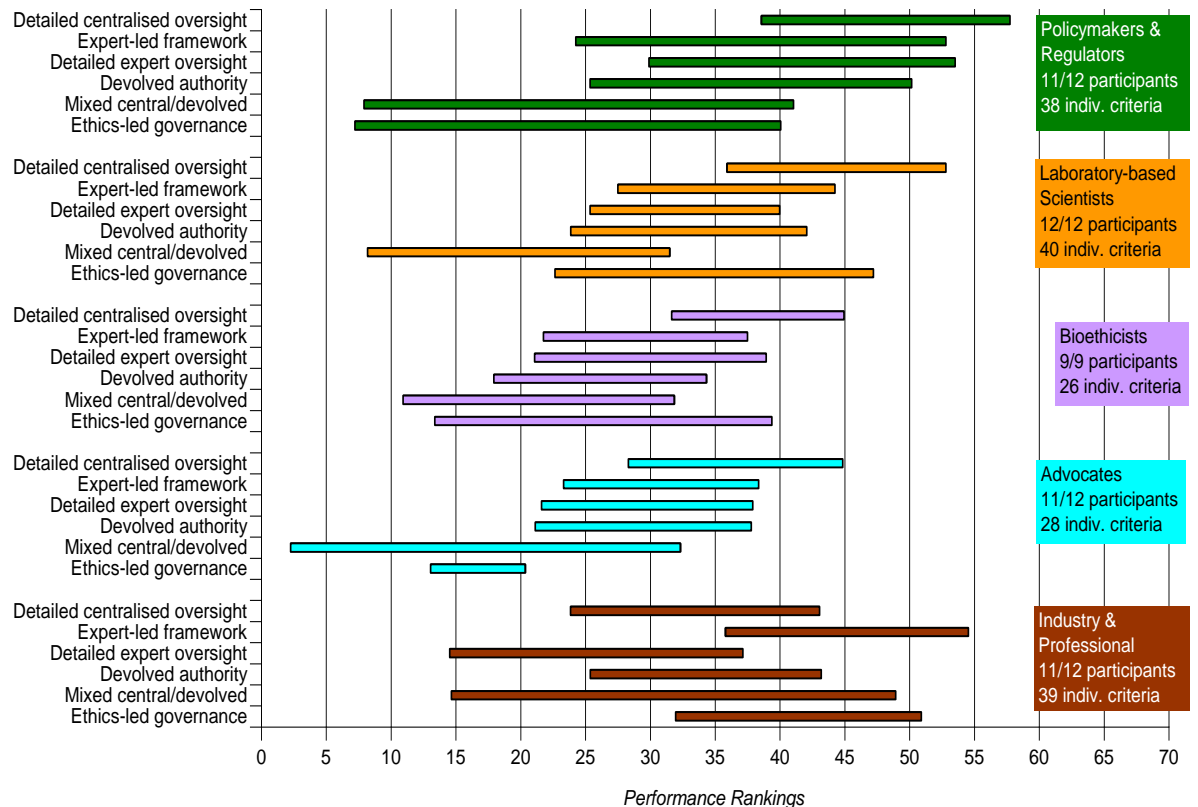


Figure K.5: Performance rankings of initial stakeholder perspectives under outcome-based issues



Rankings for moral and ethical awareness criteria

The figures below show the performance rankings for different perspectives under ‘moral and ethical awareness’ criteria.

Figure K.6: Rankings of UK and US perspectives under ‘moral and ethical awareness’ criteria

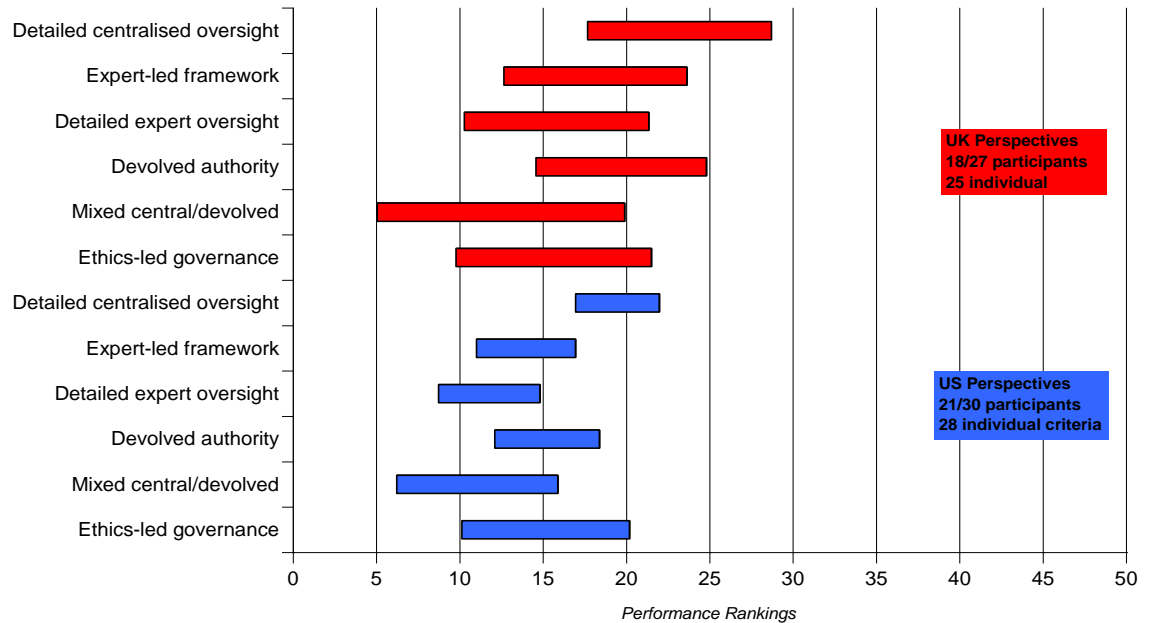


Figure K.7: Rankings of UK and US perspectives under ‘moral and ethical awareness’ criteria

